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Part III & IV

THE SAFETY OF FOOD IMPORTS: FRAUD AND DECEPTION IN THE FOOD IMPORT PROCESS—PART III AND IMPROVING THE SAFETY OF FOOD IMPORTS—PART IV

HEARINGS

BEFORE THE

PERMANENT
SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

PART III AND IV

SEPTEMBER 10, 24 AND 25, 1998

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THE SAFETY OF FOOD IMPORTS: FRAUD AND DECEPTION IN THE FOOD IMPORT PROCESS—PART III

THURSDAY, SEPTEMBER 10, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:33 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins, Domenici, Levin, Lieberman, and Durbin.

Staff Present: Timothy J. Shea, Chief Counsel/Staff Director; Mary D. Robertson, Chief Clerk; Christopher A. Ford, Senior Counsel; Mary G. Mitschow, Counsel; Don Mullinax, Chief Investigator; Kirk E. Walder, Investigator; Stephanie Smith, Investigator; Eric Eskew, Investigator (Detailee, HHS–IG); Lindsey E. Ledwin, Staff Assistant; Pamela Marple, Minority Chief Counsel; Brian Benczkowski (Senator Domenici), Michael Loesch (Senator Cochran); Steve Abbott (Senator Collins); Pam Muha (Senator Specter); Patricia Dody (Senator Cochran); Tyler Wegmeyer (Senator Cochran); Chris Dockerty (Senator Thompson); Linda Gustitus (Senator Levin); Nanci Langley (Senator Akaka); Marianne Upton (Senator Durbin); Kevin Landy (Senator Lieberman); Myla Edwards (Senator Levin); and Maureen Barry (Senator Roth).

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Good morning. The Subcommittee will please come to order.

Today, the Permanent Subcommittee on Investigations holds its third in a series of hearings on the safety of imported food. This morning, we will examine how fraud and deception in the food import process can allow contaminated and dangerous food into this country and onto the dinner tables of American families.

At our first hearing in May, the General Accounting Office reported on the current state of the food import system and concluded that "Federal agencies cannot ensure that the growing volume of imported food is safe for consumers." The GAO's findings represent a serious indictment of some Federal efforts to ensure the safety of imported food and are particularly critical of the Food and Drug Administration's inspections system.

One of GAO's most disturbing findings, one of the findings that we will focus on today, is that "weaknesses in controls over food imports enable entry of unsafe products" into the United States. In other words, even if Federal inspectors discover contaminated food, effective controls are not in place to prevent these unsafe products from entering the American marketplace.

The GAO reported that the FDA's system for controlling the importation of unsafe foods has a history of circumvention by unscrupulous importers. At our May hearing, we heard briefly about Operation Bad Apple, a recent Customs Service review of import procedures at the Port of San Francisco. The bottom line of that investigation is extremely troubling. Customs found that 70 percent of the food shipments that the FDA had ordered destroyed or reexported because they were unsafe actually entered U.S. commerce. The fact that the FDA inspects fewer than 2 percent of the 2.7 million shipments of food into the United States each year is in itself a cause for concern, but we now find that even if the FDA discovers contaminated food, there is a good chance that this unsafe food will end up in grocery stores and restaurants across America.

Serious deficiencies in the FDA's inspection system allow some imported food—including contaminated and unsafe food—to be sold in domestic commerce before the FDA inspects or releases the shipments. In some cases, the importers simply sell the food before FDA is able to inspect or release it. In other cases, unscrupulous importers fail to reexport or destroy the unsafe products after they have been rejected by the FDA. The fact that the FDA does not take custody of suspect shipments facilitates the evasion of its orders, according to the GAO.

After hearing the testimony from the GAO at our May hearing, I asked the agency, as well as the Subcommittee staff, to dig deeper into the weaknesses of Federal controls over shipments of imported food. I asked them to identify ways to strengthen these controls.

In this regard, a key question that we will explore today is whether existing penalties provide a meaningful and sufficient deterrent or whether they are simply considered a cost of doing business. This hearing will examine the specific ways in which unscrupulous importers exploit weaknesses in the current system to evade food safety protections and consider possible options to improve controls over food imports.

Our focus is on the deficiencies in the current system that allow fraud and deception to flourish. Fraud, as with criminal activity in general, occurs when two elements converge, motive and opportunity. Motive for criminal activity in most cases is the age-old vice of greed. The Subcommittee's initial investigation indicates that greater profit, the low risk of apprehension, and insufficient penalties provide the motive for unscrupulous importers to ship unsafe food into this country. Opportunity with respect to fraud in the food import process is the ability of unethical importers to exploit and evade the inspection process.

When the current system gives criminals the opportunity to evade import controls and bring tainted food into our country, the impact is not merely monetary, as it is with most fraud-related crimes. Here, the impact is far greater, affecting the health and

safety of Americans who consume imported food. And, as we learned at our previous hearings, the very old, the very young, and the very ill are most at risk for foodborne illnesses that cause as many as 9,000 deaths in this country each year.

To help us continue this important investigation, we will hear this morning from officials of the GAO who will present their findings from a review of import controls that I requested following our overview hearing in May. We will also hear from officials of the U.S. Customs Service, the first-line agency responsible for the inspection and handling of imported goods.

Finally, we will hear this morning from an individual who operated on the inside of the food import business as a customs broker. He was recently convicted during a Customs Service criminal investigation and he has been cooperating with authorities in a special operation that resulted in the arrest and conviction of several individuals for importing unsafe foods into the United States.

We look forward to hearing from our witnesses this morning so that we can identify the weaknesses in import controls and examine ways to close the loopholes used by unscrupulous importers.

Americans enjoy having access to a wide variety of foods from around the globe throughout the year. Our goal is to ensure that America's food supply remains the safest in the world and that the growing tide of imported food does not swamp our already overburdened and ineffective food safety system.

It is now my pleasure to recognize Senator Levin for any comments that he may wish to make.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you, Madam Chairman, for conducting this series of hearings on a very important subject. Your leadership is critically important to the Nation and we commend you for it.

Ensuring the safety of the Nation's food supply, both domestic and imported, should be a top priority for Congress and for the country.

We know that Americans are eating increasing amounts of imported food, especially imported produce. Statistics collected by the GAO reflect that Americans consume 50 percent more imported vegetables today than they consumed in 1980. These numbers reflect the increasing attention that we must pay specifically to ensuring that imported food is safe for the consuming American public.

We looked earlier at Federal food safety programs in general. We learned that Federal inspection of imported foods today is inadequate. Enforcement is understaffed. Remedies for violations of the food safety laws are weak.

The strain on Federal food safety inspection resources is obvious. In 1992, the FDA was able to inspect 8 percent of imported foods, but in 1997, it was able to inspect less than 2 percent of imported foods. So our food safety inspection system is being overwhelmed, both by the amount of imports and by imports potentially contaminated with emerging pathogens, as well, that are unfamiliar to our food safety agencies. So we have got to update and strengthen the safety net for food that Federal agencies are supposed to provide to our people.

The impact that one fraudulent actor, domestic or foreign, can have on the lives of innocent U.S. consumers was dramatically illustrated last year in Michigan when there was an outbreak of Hepatitis A. A food brokerage company that was based in California called Andrew and Williamson Sales Co., falsely certified to the U.S. Department of Agriculture that certain strawberries that it had were domestic food products. They did this knowing that the strawberries were grown in Mexico and then, therefore, were not eligible to be sold to the Federal School Lunch Program.

But those tainted frozen strawberries were served in a school lunch program, and as a result, about 200 Michigan school children contracted Hepatitis A. Andrews and Williamson paid a $1.3 million civil penalty and about a third of a million in criminal fines. That is an unusually severe one, and appropriately severe. Too often, companies that do this are let off with a slap on the wrist or very little penalty at all.

Today, we are going to examine a number of fraudulent schemes that are perpetrated by food importers. These schemes, according to the GAO, are more prevalent among importers who bring into the country foods for which the FDA has jurisdiction—fruit, vegetables, and seafood—than among importers of meat and poultry, over which the Department of Agriculture has jurisdiction.

Limited resources, lack of direct authority to control or hold food shipments, and lack of effective deterrents seem to be the real issues in the fight against food importer fraud.

Inspection personnel and resources are reduced while the number of imported food shipments continue to increase. The FDA, in contrast to the Federal Safety and Inspection Service of the Department of Agriculture, has no legal authority to require food importers to hold shipments in FDA-controlled warehouses pending release approvals. That should change.

Finally, criminal remedies and bonding requirements, largely are the only relevant legal remedies, have proven totally ineffective, according to the GAO, because the possibility of criminal prosecution is too remote or because forfeited bond amounts are too insignificant to deter unscrupulous importers. It just is too profitable at the moment to engage in these schemes. We have got to take the profit out of it. Hopefully, these hearings and this testimony will help us take the profit out of fraud and out of the schemes which endanger the health of the American public.

[The prepared statement of Senator Levin follows:]

PREPARED STATEMENT OF SENATOR LEVIN

Thank you, Madam Chairman, for conducting this series of hearings on a very important topic of the safety of imported food. Ensuring the safety of the Nation's food supply—both domestic and imported—should be a top priority for Congress and for the country. In announcing the establishment of a Council for Food Safety, President Clinton recently said that we should all be committed to ensuring that the American people enjoy the safest possible food.

We know that Americans are eating increasing amounts of imported food, especially imported produce. Statistics collected by the GAO reflect that Americans consume 50 percent more imported vegetables today than they consumed in 1980. These numbers reflect the increasing attention that we must pay specifically to ensuring that imported food is safe for the consuming American public.

We started off this series of hearings by examining the Federal food safety system generally. At the first hearing, we learned that Federal inspection of imported foods

today is inadequate: Enforcement is understaffed and remedies for violations of the food safety laws are weak. The strain on Federal food safety inspection resources is apparent. In 1992, the FDA was able to inspect 8 percent of imported foods, while in 1997, it was able to inspect less than 2 percent. Our food safety inspection system is being overwhelmed by both the amount of imports and by imports potentially contaminated with emerging pathogens that are unfamiliar to our food safety agencies. It is clear that the food safety net created by Federal agencies and existing Federal statutes needs to be updated and strengthened.

Today we are examining instances of food importers—foreign or domestic companies that bring food into the United States—purposefully attempting to bypass U.S. food safety inspection laws. The direct result of this conduct, of course, is to release food into the U.S. food supply that has a significantly higher probability of being tainted and of sickening U.S. consumers. These companies are profiting at the expense of U.S. consumers.

The impact one fraudulent actor—domestic or foreign—can have on the lives of innocent U.S. consumers was dramatically illustrated last year when an outbreak of Hepatitis A in my home state of Michigan occurred. A U.S. food brokerage company based in California called Andrew and Williamson Sales Co., falsely certified to the U.S. Department of Agriculture that certain strawberries it had were domestic food products. Andrew and Williamson did this, knowing that the strawberries were grown in Mexico and then, in order to sell the frozen strawberries to the Federal school lunch program.

The tainted frozen strawberries were served in a school lunch program and as a result, about 200 Michigan school children contracted Hepatitis A. Andrew and Williamson paid a $1.3 million civil penalty and $350,000 in criminal fines and restitution for its conduct. The company was also debarred from selling to the U.S. Government for 3 years. Its president was recently sentenced to 5 months imprisonment and 5 months home detention for his role in the affair, and paid a $13,000 criminal fine. In trying aggressively to make a sale of food, this company caused incalculable suffering for these Michigan victims.

Today, we are going to examine a number of fraudulent schemes perpetrated by food importers. These schemes, according to the GAO, are more prevalent among importers who bring into the country foods for which the FDA has jurisdiction—fruit, vegetables, and seafood—than among importers of meat and poultry, over which the Department of Agriculture has jurisdiction. These importers, according to GAO, put U.S. consumers' health at risk by engaging in such schemes as substitution and port shopping. Some importers have come up with many ways to try to beat the U.S. inspection system.

Limited resources, lack of direct authority to control or hold food shipments, and lack of effective deterrents seem to be the real issues in the fight against food importer fraud. Inspection personnel and resources are reduced while the number of imported food shipments continue to increase. The FDA—in contrast to the Federal Safety and Inspection Service of the Department of Agriculture—has no legal authority to require food importers to hold shipments in FDA-controlled warehouses pending release approvals. Finally, criminal remedies and bonding requirements, largely the only relevant legal remedies, according to GAO have proven ineffective, because the possibility of criminal prosecution is too remote or because forfeited bond amounts are too insignificant to deter unscrupulous importers. It is profitable for them to engage in these schemes.

The FDA should have the authority to hold food shipments and the authority to select testing labs. We also need to strengthen the penalties available for engaging in this type of fraud: We need to increase bonding requirements or authorize civil penalties as well as criminal penalties for this type of behavior. Further, we need to provide food safety agencies, additional resources so that they can carry out their inspection duties. I was pleased that Senator Harkin's amendment in July to the Agriculture Appropriations bill which restored funds to the FDA and Department of Agriculture for inspection activities, as well as other food safety activities, was successful.

We cannot let it pay for food importers to beat the U.S. import inspection system by fraudulent behavior at the expense of the consuming American public.

I thank the witnesses for being here today and look forward to hearing their testimony.

Senator COLLINS. Thank you very much, Senator Levin.

Senator Lieberman, welcome.

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Thank you, Madam Chair. Thank you for holding another in this series of very important and, in the first instance, just plain informative hearings examining the safety of our imported foods.

I am going to keep my remarks brief this morning, but I do want to emphasize how disturbed I was by the reading that I have done of the materials our staff has prepared for this hearing. At the last hearing in early July, we learned how an undetectable parasite hidden in the folds of a raspberry can cause an accidental outbreak of illnesses all across the country. Today, in contrast, we will hear that shameless food importers intentionally expose our population to dangerous foodborne illnesses.

What kind of person, upon being informed that his shipment of food was unhealthy for human consumption, that it was rotting or already rotten or clearly contaminated with salmonella, would nevertheless conspire to have it admitted into our country, into our marketplace, and onto our dinner tables? Obviously, one who has no personal scruples and, therefore must be subject to the law.

The schemes that we will hear about today will leave no doubt of these people's specific criminal intentions, nor of their underlying and all too common motivation, which is exactly what Senator Collins called it, greed, unlimited greed. Why are we not treating these malefactors as criminals, considering that their actions pose a genuine threat to public health?

Well, as I read the record, in some cases, we are, but it appears that the Federal Government has neither a system in place nor the necessary resources to mount an effective defense against the fraudulent importation of unsafe foods. The FDA, for one, has clearly been overwhelmed as its responsibilities have increased with the enormous increase in foods imported into our country. I repeat the statistic that Senator Levin mentioned. The FDA can physically inspect only 2 percent of the imported food products for which it is responsible, which obviously means, conversely, that almost all of the imported food products which the FDA is charged with inspecting reach us uninspected.

As the prepared testimony of today's witnesses demonstrates, even when the FDA conducts inspections, an importer wishing to evade the law can do so with the simplest and crudest of Ponzi schemes. He can just keep one untainted good shipment, which he presents to the FDA whenever the FDA tries to examine other suspect food products, and the FDA cannot tell the difference. Now, that is not much of an inspection system to protect American consumers.

I was startled to learn in reading the materials for this hearing, that an importer who is supposed to be disposing of tainted food by shipping it out of the country under an order to do so can instead substitute garbage for the rejected food and release the food shipment into our markets with little or no fear of detection. Or an importer can simply step up and pay the small fines imposed by the law when he is caught as a cost of doing business and then continue to release his harmful products into the marketplace. This is an area where the law seems toothless, and, therefore, food consumers are protection-less.

I think the only reason why there is not more widespread outrage at this is that there is not more widespread knowledge of the current status of inspection. We actually have no idea how many thousands of untraced cases of food poisoning are caused by the legal loopholes that the system currently leaves unfilled.

I thank you, Madam Chair, for playing a critical role here in bringing these food health and safety problems to our attention, and I also thank our witnesses for the work they have done and for appearing today. I am looking forward to their testimony. Thank you.

Senator COLLINS. Thank you very much, Senator Lieberman.

Senator Durbin, I would like to call upon you for any comments you might have.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Madam Chairman. I thank the panel that has joined us today and I will be very brief.

I am happy that we are continuing this investigation into the question of food safety, particularly in imported food. As I have mentioned in previous meetings, it is a topic that I have been focusing on now for about a dozen years, and I think that the current system of inspection, as good as it is, can be dramatically improved.

The testimony we are about to hear today is going to suggest some unscrupulous and, frankly, illegal conduct on the part of those who are exporting food to the United States. I hope that we will not only be shocked by this, I hope we will be moved by it to do something, to have more inspections, to have better inspections, to have effective enforcement and prosecution and real penalties.

I hope when this is all said and done that this Congress will rise to the occasion and the Senate will lead in letting the word go out across the world that as the United States is a great opportunity for sales and a great marketplace, it is also a country that is very serious about its standards and its enforcement. We are going to protect the health of American consumers. We are going to put the cops on the beat, as needed, and we are going to enforce the laws stringently.

Thank you, Madam Chairman.

Senator COLLINS. Thank you, Senator Durbin.

I am pleased now to welcome our first panel of witnesses this morning. The panel includes officials from the General Accounting Office and the U.S. Customs Service. The GAO is represented by Lawrence Dyckman, who is the Director of GAO's Food and Agriculture Issues Division. Accompanying him are Keith Oleson and Dennis Richards. I would like to compliment the GAO for its excellent work in this area and for its extensive cooperation with the Subcommittee.

I would also like to welcome our Customs Service officials this morning. Mr. Richard Hoglund is the Deputy Assistant Commissioner for the Office of Investigations. He is accompanied by Mr. Philip Metzger, the Director of the Trade Compliance Team. The Customs Service plays a critical role in the enforcement of regulations concerning the importation of food.

Pursuant to Rule 6 of the Subcommittee, all witnesses, as those of you who have been here before know, are required to be sworn in, so I would ask that you please stand and raise your right hand.

Do you swear that the testimony you will give before the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. DYCKMAN. I do.

Mr. OLESON. I do.

Mr. RICHARDS. I do.

Mr. HOGLUND. I do.

Mr. METZGER. I do.

Senator COLLINS. Thank you. Mr. Dyckman, we are going to start with you this morning. I understand that you are going to be presenting the GAO's testimony and the two gentlemen accompanying you will be available for questions.

TESTIMONY OF LAWRENCE J. DYCKMAN,[1] DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE; ACCOMPANIED BY KEITH OLESON, SAN FRANCISCO REGIONAL OFFICE, U.S. GENERAL ACCOUNTING OFFICE; AND DENNIS RICHARDS, SAN FRANCISCO REGIONAL OFFICE, U.S. GENERAL ACCOUNTING OFFICE

Mr. DYCKMAN. Thank you. Good morning, Madam Chairman and Members of the Subcommittee. Mr. Oleson and Mr. Richards are from our San Francisco Regional Office and they have spent several years reviewing food safety issues. I am new to the area, but I am very happy to be here today.

We are pleased to be here today to testify on Federal agencies' efforts to prevent unsafe imported foods from entering the U.S. market. With the number of imported food shipments increasing, more than doubling over the past 6 years, ensuring the safety of these imported foods becomes even more challenging.

As we reported to you in May, we found weaknesses in Federal agencies' controls over shipments of imported foods that allow unsafe foods to enter domestic commerce. In response to our earlier work, you asked us to obtain additional information on the extent to which Federal controls ensure that food importers present shipments for inspection when required and that refused shipments entry are destroyed or reexported. You also asked us to identify ways to strengthen these controls.

In summary, FDA's current controls provide little assurance that shipments targeted for inspection are actually inspected or that shipments found to violate U.S. safety standards are destroyed or reexported. Importers, rather than FDA, retain custody over shipments throughout the import process. Thus, some importers have been able to substitute products targeted for inspection or for products that have been refused entry and were to be reexported or destroyed.

Moreover, the U.S. Customs Service and FDA do not effectively coordinate their efforts to ensure that importers are notified that their refused shipments must be reexported or destroyed.

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[1] The prepared statement of Mr. Dyckman appears in the Appendix on page 109.

Finally, Customs penalties for circumventing inspection and disposal requirements provide little incentive for compliance because they are too low in comparison with the value of the imported products or they are not imposed at all.

As a result of these weaknesses, shipments that fail to meet U.S. safety standards were distributed in domestic commerce.

As I indicated, unscrupulous importers can bypass FDA inspections. For example, in a San Francisco operation called Shark Fin, Customs and FDA found that importers had diverted trucks en route to inspection stations so that suspect products could be substituted with acceptable products. According to Customs investigators, the operations revealed that, among other things, six importers were sharing the same acceptable product when they had to present the shipment for inspection, a practice known as banking, or as Senator Lieberman pointed out, a Ponzi scheme.

In a follow-up operation called Operation Bad Apple, Customs and FDA again found substitutions and other serious problems.

Substitution problems occur after inspections, too, when importers are ordered to redeliver refused shipment for destruction or reexport. For example, during a 9-month period in New York, Customs found discrepancies, including instances of substitutions, in 31 of 105 refused shipments selectively examined.

Several factors contribute to FDA's and Customs' problems in ensuring that targeted shipments are actually inspected and that refused entries are properly disposed of. First, unlike FSIS, under FDA's legislative authority, importers are generally allowed to maintain custody of the shipments throughout the import process, thus providing importers with the opportunity to circumvent controls.

Second, again, unlike FSIS, which is part of the U.S. Department of Agriculture, imported food shipments under FDA's jurisdiction are not required to contain unique identification marks and FDA does not stamp products as "refused entry". This is a basic internal control which is lacking.

Third, importers of FDA-regulated products are given 90 days to reexport or destroy refused entries, and again, this is twice the amount of time the Department of Agriculture gives its importers. Obviously, with 90 days, an unscrupulous importer has more than enough opportunity to arrange for substitution.

We also found that at five of the eight ports we examined, Customs and FDA do not effectively coordinate their efforts to ensure that importers are ordered to redeliver refused shipments for disposal. For example, at two of these ports, Los Angeles and New York, Customs was unaware of FDA refusals for from 61 to 68 percent of the shipments we reviewed, and when refused shipments are not properly disposed of, they are likely to have entered domestic commerce.

For example, according to a New York Customs official, 48 of the 63 cases that we looked at did not have an FDA refused notice and, therefore, were presumably released into commerce because Customs did not issue a notice to the importer to redeliver. In these cases, I might add, we found no documentation in Customs files that these products were either reexported or destroyed, which adds more credence to what Customs officials told us. I might add

that 11 of the 48 New York cases and 8 of 21 similar cases in Los Angeles were refused entry because they contained salmonella, a bacteria that we all are aware of can cause serious illness.

Our review also showed that Customs penalties for failure to redeliver refused shipments do not effectively deter violations because they are either too low compared to the value of the product or simply not imposed at all. In some cases, Customs does not impose the maximum allowable penalty, three times the declared value, because it exceeded the value of the bond that the importer posted. In other cases, Customs did not assess as severe a penalty as the agency guidelines suggest because officials at these ports were unable to identify repeat offenders and penalize them accordingly.

Customs and FDA officials and importer association representatives suggested ways to strengthen controls over imported foods as they moved throughout the import procedures. Each of these suggestions has advantages and disadvantages. We do not make any specific recommendations at this hearing, and I will run through the suggestions, but I understand the Subcommittee will be holding another hearing in a few weeks and it might be a good opportunity to ask Customs and FDA and other witnesses what they think of these suggestions.

First, for certain importers that have repeatedly violated import controls, Customs and FDA could work together to ensure that substitution does not occur before or after inspection. For example, FDA could target problem importers and Customs could order that importer's shipments be delivered by bonded trucks to an independent Customs-approved bonded warehouse pending inspection or disposal.

Second, Customs and FDA could adopt variations on the controls that FSIS uses for meat and poultry imports. To help prevent substitution before inspection, FDA could require that shipments of importers or products with a history of violations will have unique identification marks on each product container and on entry documents filed with Customs. To help ensure shipments refused entry are actually destroyed or reexported, the FDA could stamp "refused entry" on each carton or container in shipments that it does not find meet U.S. safety requirements.

Third, Customs and FDA could develop a method of ensuring that importers whose shipments are refused entry into the United States are issued notices to redeliver their cargo. One way for Customs to do this is to retrieve information from its own database on FDA refusals.

Fourth, the Congress could reduce the 90-day period allowed for redelivery of FDA-refused shipments to require importers to dispose of refused shipments more quickly and more in line with FSIS requirements.

Fifth, Customs could raise its penalties for repeat violators to make them more effective deterrents, and my full statement contains various ways in which Customs and FDA can do that.

Madam Chairman and Members, this concludes my statement. We will be happy to answer any questions you or other Members may have.

Senator COLLINS. Thank you very much.

We will now hear from the Customs officials, and I believe that, Mr. Hoglund, you are going to be presenting for the Customs Service. Please proceed.

TESTIMONY OF RICHARD J. HOGLUND,[1] DEPUTY ASSISTANT COMMISSIONER, OFFICE OF INVESTIGATIONS, U.S. CUSTOMS SERVICE; ACCOMPANIED BY PHILIP METZGER, OFFICE OF FIELD OPERATIONS, U.S. CUSTOMS SERVICE

Mr. HOGLUND. Good morning, Madam Chairman, Members of the Subcommittee. Thank you very much. It is a pleasure to be here today to speak about some of Customs investigative efforts in recent years focusing on the illegal importation of tainted foodstuffs. I am well aware of this Subcommittee's oversight work in the area, including hearings held earlier this year.

While my statement will primarily highlight some recent cases and the schemes uncovered, I thought it would be helpful to the Subcommittee to give a brief overview of Customs' mission, responsibilities, and challenges.

The U.S. Customs Service enforces more than 400 laws for more than 40 U.S. agencies, including the Food and Drug Administration and the USDA. In many cases, Customs has no or very limited independent statutory or regulatory authority, but instead derives the authority to prohibit importation, exportation, or to seize merchandise from directions and orders given by the regulating agencies. Indeed, Customs' work with the FDA is very much like our work with the Departments of State, Commerce, and Energy in the enforcement of U.S. export laws governing weapons, technology, and nuclear items.

Customs faces what is perhaps the most diverse challenge of any law enforcement agency in the world. Consider that the U.S. Customs Service combats child pornography, narcotics smuggling, money laundering, arms trafficking, stolen automobile exports, theft from cargo, revenue fraud, intellectual property rights violations, trafficking in endangered species, importations of slave and forced child labor goods, and the importation of tainted foodstuffs, to name just a few.

Combatting the importation of tainted foodstuffs presents a unique situation in that actual smuggling or false invoicing at time of entry is not necessary. Whereas a shipment of cocaine must be sealed in a false compartment or within otherwise legitimate merchandise, tainted foodstuffs can hide in plain sight. That is to say, for the most part, where they are from or what they are is not the issue as much as whether they are clean or tainted.

Customs recognizes the threat that contaminated food represents to our Nation. Indeed, public health and safety is a priority area under our agency's trade enforcement strategy. Customs has worked some 134 investigations related to tainted foodstuff importation since September of 1993. I would like to take a few minutes now to outline a few of these cases. Before I do so, though, it is important to note that these cases rely largely on the outstanding cooperative relationship between FDA's investigative offices and the Customs Service.

[1] The prepared statement of Mr. Hoglund appears in the Appendix on page 129.

Operation Shark Fin has been mentioned, and I will go into a little bit of detail on that investigation. In April 1996, the Special Agent in Charge, San Francisco Office, developed information regarding the illegal importation and smuggling of adulterated foodstuffs and the bribing of public officials. Subsequently, in November 1996, a joint undercover investigation was initiated with the FDA Office of Criminal Investigations and the Department of Health and Human Services Office of Inspector General. The ensuing 10-month investigation disclosed that a licensed Customhouse Broker and two FDA consumer safety inspectors had facilitated a scheme to allow adulterated foodstuffs, such as real and imitation shark fins, abalone, birds' nests, dried oysters, and scallops, to illegally enter the commerce of the United States from Asia.

This is how it worked. In December 1996, Customs opened an uncover brokerage business utilizing the Customhouse Broker as a full-time employee. The storefront was used to monitor and record illegal transactions between the broker and the targeted individuals. The operation only focused on individuals with whom the broker had conducted illegal transactions with in the past. During the operation, there were more than 100 undercover contacts with various targets.

During the undercover negotiations, several targets expressed interest in offering monetary bribes to an FDA employee in exchange for utilizing his or her position to sign FDA entry notices containing fraudulent information. This action would allow for the release of the FDA-regulated food shipments without the required inspection by FDA. An undercover agent posing as an FDA inspector was introduced to the targets and the targets ultimately offered to bribe the undercover agent in an attempt to circumvent Customs and FDA examinations.

This investigation determined that various schemes had been used to get the illegal merchandise into the country. The intent of these schemes was to circumvent inspection by Customs and FDA. The importers would switch the contaminated merchandise with clean merchandise—I believe that "banking" was referred to earlier—when an inspection was required. The switch would occur between the time the cargo was moved from the port where the vessel was docked and the location of the warehouse for inspection. If samples for lab analysis were to be taken at the importer's premises, the importer would have a small quantity of this clean product available and would take the samples from there to submit for testing.

In the event that merchandise was appropriately inspected, tested, and found to be contaminated, the importer has the option of reexporting the merchandise from the United States or to destroy the merchandise. Should the importer elect to reexport, the same merchandise would be imported back into the United States at a later date. In the event that the importer elected to destroy the merchandise, substituted merchandise would be destroyed instead of the required merchandise. The importer would usually destroy trash similar in weight to merchandise they were supposed to destroy.

Operation Bad Apple was developed by the Office of Field Operations of the Customs Service in San Francisco as an outgrowth of

Operation Shark Fin. Overall, this operation was intended to measure the compliance with import requirements by companies importing foodstuffs into the United States in the Port of San Francisco and to take enforcement action against willful and repeat violators. This operation was conducted with the assistance and cooperation of the FDA during July 21, 1997 through August 4, 1997.

In order to examine imports of foodstuffs, selectivity criteria were developed to notify the inspector electronically of a foodstuff import. During Operation Bad Apple, 1,026 shipments of merchandise matched these criteria. Based on these matches, 429 shipments containing 1,400 line items were targeted for examination. The examinations resulted in a total of 305 discrepancies discovered, and that is the entire array of discrepancies. However, only a total of 33 shipments were denied entry into the United States for not meeting FDA requirements. In addition, 13 civil penalties were issued against the importers, totaling approximately $200,000.

As a result of these operations, the Port of San Francisco has identified the top 10 high-risk importers of foodstuffs. These importers are being monitored closely for compliance with FDA import requirements.

Another investigation was Sigma International. This was a joint investigation conducted by the Special Agent in Charge, Tampa, Florida office and the FDA Office of Criminal Investigations. It was an investigation into a scheme by which Sigma International, a large-scale importer, four of its officers, and one of its foreign purchasing agents illegally imported Indian-processed shrimp valued at approximately $4.5 million via false and fraudulent documents. These documents were provided to the government in order to avoid compulsory FDA laboratory testing, as well as examination of its merchandise. The merchandise consisted of decomposed shrimp that had been chemically treated to mask the decomposition.

The information uncovering the scheme was provided by an FDA inspector after his review of entry documents and examination of shrimp imported by Sigma. The company was soaking the decomposed Chinese shrimp purchased in India in a solution of chlorine and copper sulfate with the intent to deceive customers by passing off the shrimp as fresh frozen. Sigma sold its shrimp to large shrimp processors, who in turn sold it to supermarkets and restaurant chains throughout the United States.

The other investigation I would like to highlight is Fresh Sea Products. In March 1996, a commercial truck entered the Otay Mesa commercial inspection facility from Tijuana, Mexico. The driver declared frozen fish products as products of Mexico. Initial Customs inspection disclosed that the fish products were really from the Orient. Further examination of the fish by Customs and FDA inspectors revealed fish from shipments which had been rejected entry into the United States by FDA 2 years earlier, in 1994.

The FDA originally rejected the shipment because it contained salmonella, botulism, and filth. This shipment was exported and stored in Mexico and then attempted to be reimported and sold to restaurants in the Los Angeles area. The shipment was ultimately seized and ordered destroyed.

Currently, there are several ongoing investigations involving the importation of tainted foodstuffs. Joint investigations are being conducted with FDA and these investigations include such schemes as the attempted reimportation where entry had been denied, switching of foodstuffs that were denied entry and were required to be exported, and foodstuffs that were mislabeled to avoid mandatory FDA inspection and testing.

I can assure the Subcommittee that this will continue to be a priority area for Customs and that we will continue to work with FDA to develop and execute effective investigative operations targeting individuals and organizations involved in tainted foodstuff importations.

Madam Chairman, that completes my prepared remarks. I would be happy to answer questions, and, of course, you introduced Mr. Metzger, who would assist in any areas that go specifically to port processing. Thank you.

Senator COLLINS. Thank you very much, Mr. Hoglund.

Before we turn to questions, I want to welcome Senator Domenici to these hearings and see if he has any preliminary comments he would like to make. Senator Domenici, welcome.

OPENING STATEMENT OF SENATOR DOMENICI

Senator DOMENICI. Thank you very much, Madam Chairperson. I have no remarks other than to, again, compliment you on these hearings. When they first started, a lot of people wondered what they were all about. They are beginning to understand, thanks to your diligence and hard work, and I do hope we learn something from it that we can implement. It is difficult to try to find a better way to do it, but I think with your leadership, we will find a better way and we will get it done better. Thank you very much.

Senator COLLINS. Thank you, Senator Domenici.

I say that after these hearings, my diet gets more and more constricted. First it was raspberries. Now it is fish, and frozen shrimp, one of my favorites. On a serious note, it really is disturbing to hear the testimony that we have accumulated over the past two hearings.

I want to get a better feel for the extent that fraud and deception contributes to the food safety problem in the United States. Mr. Dyckman, I know that the GAO has done a lot of work reviewing the shipments at the ports of entry, and it is my understanding that you found substantial percentages in the sampling that you did of rejected food products, food products that have been rejected by the FDA, and keep in mind that the FDA is looking at fewer than 2 percent of all the shipments. But these are food shipments that have been rejected and yet are finding their way into the American marketplace.

Could you give the Subcommittee some idea of how widespread this problem is? Is it confined to one or two major ports or did your review find that this was a problem at virtually every port of entry?

Mr. DYCKMAN. Madam Chairman, as you indicated, it is difficult to quantify the problem without doing special operations at all ports all the time. But I have to tell you that the internal control weaknesses that we observed, they exist at every port. We have

looked at controls of FDA-regulated products at eight ports. We met with FDA beforehand. We asked them if these were representative ports. They said they were. So we have no reason to believe that the problems that we identified and that Customs have identified through special operations do not exist at just about every port.

You indicated, and I might add, that when Customs does a special operation, they always uncover fraud and deception and substitution. So my answer is, yes, these are pervasive problems.

Senator COLLINS. And that suggests to me an indictment of the system that we are using, that there are systemic weaknesses that repeatedly allow unethical importers, that allow criminals to evade the inspection process. Is that a fair conclusion?

Mr. DYCKMAN. Yes. The internal control, or the control problems that we identified, definitely give opportunities or present opportunities for unscrupulous importers to bypass the system.

Senator COLLINS. Mr. Hoglund, I want to talk further about a specific case that you indicated because it seems so egregious and shocking to me. As I understand it, you looked at a case where fish in 1996 came in from Mexico and it turned out that Customs inspection disclosed that the fish products that were being inspected in 1996 were not from Mexico but were from Asia and, in fact, that that fish came from shipments that had been rejected by the FDA in 1994, 2 years before, is that correct?

Mr. HOGLUND. Yes, ma'am, that is correct.

Senator COLLINS. You indicated that in this case, the company president pleaded guilty for the import of adulterated food into the United States. Could you tell us what the sentence and penalties were in this case?

Mr. HOGLUND. I will look for that. I may have that handy.

Senator COLLINS. I think it is on page 7 of your prepared testimony. It is my understanding that there was only a 1-year probation and 50 hours of community service in this case. Can you verify that?

Mr. HOGLUND. The violator was sentenced to 1 year probation and 50 hours of community service, that is correct.

Senator COLLINS. I am incredulous that that is all the penalty was, that someone took 2-year-old fish that had been rejected because it was contaminated with botulism, as I understand it, is that correct?

Mr. HOGLUND. Yes, that is correct.

Senator COLLINS. In other words, this fish could have killed someone, or at the very least, made people extremely ill. It was then held for 2 years, which certainly did not improve the quality of the fish, reexported into the United States, and the person who did this only got a year's probation and 50 hours of community service? Do you think that that was an adequate penalty?

Mr. HOGLUND. Well, I can only assume that the sentencing guidelines were followed by the judge in that case.

Senator COLLINS. I am not questioning that, and I am certainly not blaming the Customs Service, which deserves credit for bringing the case forward, but do you personally believe that that was a sufficient penalty or should the laws be far tougher? Do you think that is really a deterrent?

Mr. HOGLUND. Well, I think it is the application, because, as was stated earlier, there is a wide range and there are violators who are sentenced to significant prison terms. So I do not know that there is not the availability of significant punishment. It is applying it.

Senator COLLINS. Mr. Oleson, do you have an opinion on this case? Is it one that you are familiar with? I know you have done a lot of work in this area.

Mr. OLESON. I am not specifically familiar with the case mentioned, but I am somewhat incredulous, as you are, Senator, that only a year probation and 50 years of community service for bringing in a tainted product that had botulism, which is a very serious contamination problem.

Senator COLLINS. It seems to me that one of the flaws that our investigation has uncovered is that the penalties are woefully inadequate to deter this kind of fraud that jeopardizes the health and safety of American citizens. That is really serious. That is not like substituting a lower quality piece of jewelry for the one that was declared. I mean, it is a serious problem.

Mr. Oleson, I want to turn to you now. It is my understanding that you accompanied the Subcommittee staff in a review of some warehouses, I think in California. Could you tell us what you saw as part of your observations in that review, please?

Mr. OLESON. Certainly. I did accompany the Subcommittee staff on a couple of inspections. I think the most recent would probably be the most illustrative.

We accompanied FDA to an inspection of a canned seafood product. The FDA inspector entered the warehouse and asked the warehouse operator or the importer where the shipment was located. They directed him to a number of pallets that were in the front entry of the warehouse, right by the front door, in fact. The inspector then went on to select his samples and do his inspection.

While he was doing that, we toured the warehouse and looked at the other products that were in there and we found two other shipments of this same canned seafood product. The markings on the boxes were from the same manufacturer, the same information was presented, and we could not determine why one shipment was looked at over the other. They were virtually identical.

So we do not know if we were actually looking at the right shipment when we got done, and I think that is the case where substitution can take place. It could have been one of the other shipments we were supposed to look at.

Senator COLLINS. If FDA just did the simple step of stamping rejected shipments with "refused entry," would that not make banking and substitution a lot more difficult to pull off?

Mr. OLESON. It would make it more difficult for products that were refused entry and are being reexported, that it would be more difficult to bring them back in or be easier for Customs to determine that the actual refused shipment was being sent out of the country. As we pointed out, in New York, they have a special program where they examine exported shipments that have been refused entry and 31 out of 105 times, they found that the product was either short, missing altogether, or was substituted with another product. That is a significant problem.

Senator COLLINS. Another weakness that GAO's report has uncovered is the fact that the importer retains control of the suspect shipment. It is my understanding that that contrasts with the system used by the Department of Agriculture, where the shipment that has been targeted is taken into custody by the Department of Agriculture. Mr. Oleson, is that correct, and could you comment on the differences and whether you believe the FDA's approach provides the opportunity for the kinds of deception that we are talking about?

Mr. OLESON. Certainly. The Department of Agriculture, or the Food Safety Inspection Service, has three major controls that differ from the Food and Drug Administration. The first is when a meat and poultry shipment comes into the country, it has to be taken to an FSIS-approved inspection station. That is a type of a bonded warehouse where it is controlled.

The shipment also must contain unique markings that are on the health certificate that must accompany the shipment. So when an FSIS inspector looks at the shipment, he can be assured that this is one in the same shipment he is supposed to be looking at.

The third area is when FSIS completes their inspection, they will stamp any refused item "refused entry". It is still controlled in that warehouse. It will not leave that warehouse until either it is released by FSIS or the refused entry has been taken care of by the importer, who has arranged for export.

FDA does not have these controls. In fact, the importer controls the shipment from the entire process, once it enters until it is released. If it is refused entry, the shipment is still at the importer's warehouse and it is up to the importer to return it back to the port, where Customs will witness either destruction or export.

There are no markings on the shipment to identify whether they are the correct shipments or not. There is no stamp of refusal, and as such, sometimes, as Customs pointed out, the importers try to reimport the "refused entry" shipment. We have two cases recently in Los Angeles where such things were found. One was on rice sticks, the other was on a tamarind fruit, where they brought them back in.

Senator COLLINS. Thank you, Mr. Oleson.

I am going to turn to my colleagues. I do have additional questions, but I will wait for another round. Senator Lieberman.

Senator LIEBERMAN. Thanks, Madam Chair.

I wanted to thank you, Mr. Dyckman, and your staff at GAO. I think you have done a first-rate investigative and reporting job here. I must say that it leaves me with a feeling that this is a very porous system. I do not underestimate the difficulty of improving it and what it will cost us to do it. In that regard, I appreciate some of your very thoughtful suggestions.

But it takes an honest and honorable importer to do it right, because the probability of being able, at least as I read your work, of being able to circumvent the system is high. If you want to do it, it is pretty easy to game the system with really dreadful consequences for a lot of people's health.

I just wanted to thank you for the work which you have done, which is very important to us as we go about our work, and I want to focus on a few parts of this.

One that struck me is what you point out are some serious flaws in communication and coordination between the FDA and the Customs Service. In what I consider to be a startling number of cases that you pointed out in New York and Los Angeles, the Customs Service was actually unaware of FDA's refusal notices for food shipments. If I am not mistaken, it was between 61 and 68 percent of the shipments GAO reviewed, Customs was unaware that FDA had put down a refusal notice.

According to your work, the GAO work, in most of the cases where the Customs Service did not receive FDA's refusal notice, the product would have been released into commerce here in this country, and I gather from your report that in a number of those cases, the products were refused by the FDA because they contained salmonella. Have I got that right, Mr. Dyckman?

Mr. DYCKMAN. Yes, you have. Unfortunately, you do.

Senator LIEBERMAN. Do you want to add anything to my telling of it and explain—go ahead.

Mr. DYCKMAN. Well, yes. We have two agencies that have unique responsibilities and they are supposed to work together. We know that they are both hard-working agencies and they mean well——

Senator LIEBERMAN. Right.

Mr. DYCKMAN [continuing]. But there is obviously an opportunity to improve their ability to detect these types of things that we have been talking about. A basic principle is that one agency knows what the other agency is doing, and unfortunately, we found in too many cases that this is not occurring.

We think the solutions are fairly simple. We have discussed these with the agencies at closeout meetings. I think they are both amenable to take corrective action to improve coordination so that Customs knows in all cases when FDA refuses a shipment so that it could send a notice of redelivery to the importer. It is a basic internal control. We hope that, in short order, it will be fixed.

Senator LIEBERMAN. Mr. Hoglund or Mr. Metzger, do you want to give a response to that, about why the Customs Service was unaware of those FDA refusal notices at such a high percentage? I mean, it is unsettling. We are talking about the basic problem. The percentage of food that FDA gets to inspect is relatively low. So even among that small universe, of those where there are refusal notices, it seems as much as two-thirds of the time, the notices are either not conveyed or for some reason Customs is not aware of them, so the food may then go out into commerce.

Mr. Metzger.

Mr. METZGER. The system as it works consists of two automated systems. There is a Customs automated system and there is an FDA automated system. Apparently, to date, the systems have not talked to each other perhaps as they should have. We have relied on manual notices or copies of those refusal notices coming to Customs. Now, we are looking into why these may not have gotten to us. However, notwithstanding that, we believe that we need to work with FDA so that we get output from the automated system, which has all of the refusals in it, so that we can act on those and not rely on the manual statements that we have been relying on to date.

As to why we did not receive them or did not get them, I do not have the information. We certainly will look into that. But I think we need to perfect the system, in any event.

Senator LIEBERMAN. And you and FDA are working on that now?

Mr. METZGER. We certainly are.

Senator LIEBERMAN. I hope you will keep the Committee posted about progress on that as soon as possible.

Mr. METZGER. We will.

Senator LIEBERMAN. Another part of this story that is hair raising, or maybe I should say in this case stomach turning, is the case that GAO makes that importers are able to bring tainted food into the American market even after the FDA has barred the import of food in another way, which is that importers have the option of reexporting barred goods, but there are cases that you cite where importers are actually substituting shipments of garbage which they are reexporting. Can you tell us a little bit more about that case, Mr. Dyckman, or any of your team?

Mr. OLESON. Yes, Senator Lieberman. This is a predecessor case to New York establishing their outbound inspection program. What they are doing is they decided to examine some shipments that were going out to determine—which Customs is responsible for doing as the insurer—that the refused shipment is either exported or destroyed. When they actually opened the container, they found that there was garbage or trash in there and not the shipment that was supposed to be. The weight was right, but the product was not.

Subsequent to that, they had found——

Senator LIEBERMAN. Excuse me. Therefore, the barred product was presumably put into the marketplace?

Mr. OLESON. That is correct, that the barred product would go ahead and be distributed to commerce.

Senator LIEBERMAN. So have they set up a system now to try to double-check that?

Mr. OLESON. Yes. In New York, they have what they call the Outbound Program, where they will target certain shipments and examine those intensively to determine whether there has been any substitution or shortages or non-redeliveries. In fact, they have a number of cases that they illustrated earlier where they found them.

However, it is quite difficult to do that. Sometimes they even had to call the manufacturer in the foreign country to determine from the best-used-by date that was on the container what the actual production date of that product was. After they got that and they made their computation, they found that the production date was subsequent to the importation date, so obviously it was not the product that was refused entry, it was another product. These are some of the things they are doing in New York. It takes a very diligent, observant Customs inspector to do that and we should praise him for his action.

Senator LIEBERMAN. Do you know whether any criminal action was taken against the importer who substituted trash for the tainted food?

Mr. DYCKMAN. We are not aware of any.

Mr. OLESON. I suggest Customs may know that answer.

Senator LIEBERMAN. Do you know, Mr. Hoglund or Mr. Metzger?

Mr. METZGER. I have no knowledge of that, but I will check that out.

Mr. HOGLUND. We can get the answer to you.

Senator LIEBERMAN. I would appreciate that.

I have just one or two more questions. Mr. Hoglund, we have heard that civil penalties are not an effective deterrent in these cases because the amounts of the bond required by law can be relatively small. Why does not the Customs Service pursue criminal charges in a greater number of cases? I mean, you have pointed out some cases here today which were successful and I admire those, but why has not Customs gone through the criminal courts in a greater number of cases?

Mr. HOGLUND. Part of the answer is that we are dealing with different sets of penalty regulations. The liquidated damages which I think you are referring to in terms of the three times the declared value, those are in line with enforcing FDA's requirements for reexport or a violation of our redelivery notice. We do have more significant civil penalties if a fraud is committed on the Customs Service under our regulations and under our laws. Likewise, the criminal penalties that have been applied in the majority of these cases have had to do with violations of Customs laws in terms of false invoicing, misdescription, in order to evade the FDA requirement. So it is a mixture, and I think Phil can explain more readily the area of the liquidated damages.

Mr. METZGER. I would tell you that the Customs Service in a large majority of cases where actions are initiated rely on the civil penalty, the bond amounts. The maximum is three times the value.

As far as pursuing criminal cases, and again, I do not want to speak for the Office of Investigations, but it would seem to me that it could be in part a resource issue. The criminal cases require a number of investigative resources. It requires a much higher level of proof, evidence, to sustain. We believe that in most cases, the civil deterrent, the monetary penalty, would suffice. Apparently, our assumption may not be correct and——

Senator LIEBERMAN. Would you agree, then, as we try to set up a system—I mean, obviously, we cannot check and inspect every piece of food coming into the country. As GAO has pointed out, we can certainly do better than we are doing now in various ways. But would not one of the ways to create better behavior by these folks who are unscrupulous now be to have more frequent enforcement of criminal penalties against those who you find to be guilty of wrongdoing?

Mr. METZGER. What we hope to do with the FDA is target likely violators, instead of just taking a broad-brush approach, zero in on those areas where we think the risk is highest, look at those more closely, and certainly, if we have violators who are repeated violators, I think we would be amenable to resorting to more of the criminal actions as opposed to just the civil actions.

But again, we are going to work with FDA on zeroing in on where the likely violations occur, that we cannot just use our resources across the board and waste them. We know there are areas where it is more likely that there will be violations and that is where we hope to focus.

Senator LIEBERMAN. I urge you to do that.

Mr. Hoglund, did you want to add something?

Mr. HOGLUND. Yes. Senator, it might be helpful, of the 134 cases, investigations, that I mentioned earlier, 62 indictments resulted from those, 47 arrests, 38 convictions, 7 court fines, 87 seizures, 17 penalties, 1 forfeiture, 3 acquittals, and 1 dismissal. Seventy cases were closed without any criminal finding.

Senator LIEBERMAN. Mr. Dyckman, just a final question. We have talked about greed obviously being the motivation here. Can you give us any idea of the amounts of money involved in these shipments? I understand they are varying sizes, but I have no idea of what kind of money can be made in this business if one is willing to break the law.

Mr. DYCKMAN. Well, I think we have a case in our testimony where the mark-up is substantial, so even if a penalty is imposed at three times the declared value, there is still ample room for profit. We were told by Customs officials that the mark-up can be 10-fold, so——

Senator LIEBERMAN. Ten-fold over the value of——

Mr. DYCKMAN. Of the declared value.

Senator LIEBERMAN. Are these normally shipments that are tens of thousands, hundreds of thousands, millions? I do not know what the value is.

Mr. DYCKMAN. Do you have a better feel for the size of the shipments that you looked at?

Mr. RICHARDS. It varied widely.

Senator LIEBERMAN. Maybe it is a hard question to answer, because they vary widely, but the point you made is an important one, particularly as related to the penalty system because of the markup.

Mr. DYCKMAN. Yes. We visited warehouses and some of the shipments are huge, more than one truckload. Depending on the type of product, they could be very valuable.

Senator LIEBERMAN. OK. Thanks very much. Thanks, Madam Chair.

Senator COLLINS. Thank you, Senator Lieberman.

Senator Durbin.

Senator DURBIN. Thank you, Madam Chairman.

Mr. Hoglund, for some perspective here, can you give me an idea of how many inspectors the Customs Service has in this area of imported food inspection?

Mr. HOGLUND. I will defer to Mr. Metzger. That is his area.

Mr. METZGER. Well, the inspectors do not concentrate in one area. We have inspectors who do cargo around the country, and I would guess the number would be about—Customs inspectors, now—about 2,500 inspectors who do cargo.

Senator DURBIN. Can you give me an idea of the volume of entries that they would inspect during the course of a year?

Mr. METZGER. The number of entries that come into the country in the course of a year is around 18 million entries. Of that number, I would estimate that the percentage examined is less than 5 percent.

Senator DURBIN. We had a hearing on this subject in May and I asked Mr. Oleson some questions then. I will have to tell you that I am disappointed in the GAO report, that it does not address the

question which I raised in the first hearing. I believe that it is fundamentally unfair to compare the Food and Drug Administration to the Food Safety Inspection Service of the U.S. Department of Agriculture without making some reference to the difference in staffing, which is dramatic. Mr. Dyckman, are you aware of that difference?

Mr. DYCKMAN. Yes, I am.

Senator DURBIN. Did you make any reference to that at all in the GAO report?

Mr. DYCKMAN. Our report, or our testimony basically addresses poor internal controls, what you do with the staff that you have. In some cases, there are legislative problems. The authorities that the Department of Agriculture has are different than FDA's. USDA's are stronger. Staffing is part of the issue. But even putting staffing aside, things like marking, things like putting things in bonded warehouses, should not directly impact the number of staff that Customs or FDA has.

Senator DURBIN. Mr. Dyckman, I do not argue with that, and I think each of your suggestions is a good one and I think they should be implemented and it should be a consistent standard, whether it is the FSIS or FDA. There are some of us who feel that this should all be under one agency, rather than spread around 6 or 12 different Federal agencies with different administrators and different rules and regulations and an absolute crazy quilt of standards when the American consumer just wants to know one basic question: Is this safe to eat? I think we ought to get down to the bottom line.

But for the record, I want to put on the record what I consider to be a dramatic quantitative difference between the FSIS and the FDA which needs to be part of this record and should be part of a GAO report. I really think it goes beyond the question of improving the procedures here, but whether we are prepared to make a commitment as a Nation to have the kind of quality inspection that we need.

First, let us talk about the volume of growth. The number of imported food products has doubled over the past 6 years. In the Food and Drug Administration, each inspector is responsible for nearly three times as many shipments today as they were 5 years ago. That is expected to increase by another 33 percent over the next 5 years. *U.S. News and World Report* did a study on this and they concluded the agency has a seemingly impossible task.

Now, let me give you the figures. We have talked about the fact the FSIS visually inspects 118,000 entries of imported meats and poultry, and physically inspects 20 percent of them, 118,000 entries. How many inspectors are at the Food Safety Inspection Service? Eighty-four.

Now, go over to the Food and Drug Administration. There are 2.7 million entries, as opposed to 118,000, of imported foods, physically inspecting 1.7 percent of them, and they have, according to Mr. Oleson's testimony in May, 463 people who are involved in that. The USDA, Department of Agriculture, has only 4 percent of the responsibility of the Food and Drug Administration. They have 84 inspectors, where the Food and Drug Administration has 463.

If we were to put a comparable number of inspectors in the Food and Drug Administration, based on the entries that are inspected by the Department of Agriculture, we would have to quadruple the number of inspectors in the Food and Drug Administration, at which point those inspectors would have more time to take a look at these shipments, more time to carefully evaluate whether somebody is gaming the system, and more time to try to determine whether or not they are dealing with the banking and other problems that we have talked about today.

When I take a look at the situation facing the Customs Service, with 2,500 inspectors, the largest of all of them, it appears that they could always use more, but they have substantially more resources, more personnel who are involved in this.

Now, here is the bottom line and why we do not talk about this on Capitol Hill. How are we going to get more inspectors in the FDA? There are two ways. One, increase their appropriation, which means spending more money here on Capitol Hill. We do not like to talk about it in a time of reducing the budget. But if we are going to be honest about it, we are going to have to. The other alternative is a user fee, saying to the people who want to export to the United States, you have got to pay for inspection so that we can be certain that the American consumers know that they are getting something safe on their tables. Then we can talk about system changes, and I think all of the system changes you have suggested are valid system changes.

But when the system is so overwhelmed—here is what the *U.S. News* and *World Report* said. "Inspectors in the FDA checking computer paper records"—they have gone to computers, because they cannot keep up with the physical inspection—"spend about 3 to 10 minutes on each shipment," and that is a computer inspection. That is not a physical inspection. And only 1.7 percent were actually inspected.

If we are going to be honest about this, and I hope we will, let us change the system, as has been suggested by the GAO, but let us also accept the responsibility to put men and women on the job in these ports. The Food and Drug Administration has 309 food safety inspectors. The others that I mentioned, 463, are laboratory analysts and the like. There are 330 ports of entry in the United States. There are fewer inspectors than there are ports of entry. Why do we have a problem? I would suggest that is part of it, Mr. Dyckman.

Mr. DYCKMAN. I do not disagree with anything you said, Senator Durbin. As a matter of fact, yesterday, we issued a report to the House Budget Committee that says many of the same things you are saying. We point out that $1 billion is being spent by the Federal Government on food safety inspections, but we question whether 25 percent of that is actually targeted to high-risk activities.

For example, the Department of Agriculture spends about a quarter-of-a-billion dollars on carcass-by-carcass inspections, looking at every carcass, and we question the risk posed to the American people that could be eliminated by doing these inspections and we suggest that possibly some of that money be redirected for other things, such as solving the imported food safety problem.

Senator DURBIN. That is exactly the point I tried to get to on consolidating this in one agency, and I would like your response to that, because if we had all of the food safety inspection under one agency, in legislation that I have introduced, we could sit down with the National Academy of Sciences or some recognized scientific organization and say, all right, let us talk about real risk. Is it necessary to inspect each beef carcass that comes in or would it be safer for the American consumer for us to focus on processed products or fruit and vegetables? What is the best investment of our money for the safety of the American consumers? If you or Mr. Hoglund would like to address this question of consolidating food safety inspection in one agency, I would appreciate it.

Mr. DYCKMAN. We have been on record, as you probably know, for many years supporting the concept and we have recommended that the Congress consider creating one agency to handle food safety in the United States. Currently, as has been pointed out, it is a patchwork among 12 to 13 different agencies and there is no one spokesperson. There is no one that is in charge of the budgets for all these agencies as it deals with food safety. The National Academy of Sciences just came out with a report and it looks like they read many of our reports, because some of the language looks very familiar to me as I have read and prepared for this hearing. So we support in concept just about everything you have said.

Senator DURBIN. Thank you for your testimony, and let me not take anything away from your recommendations. I think they are all very valid. But I think we have got to get down to the bottom line here. We can make changes, modifications in procedures and they will undoubtedly marginally improve the situation. But if we are serious about this and if we are truly going to be a Nation more and more dependent on imported food, I think we have to be serious about it and we have to go down to some basic questions. Are we willing, first, to streamline this and to make it more efficient with one agency, and second, will we put the resources into inspection to make sure that we can guarantee the American people that they have safe food on their tables?

Thanks, Madam Chairman.

Senator COLLINS. Thank you, Senator Durbin.

For the next round of questions, I am going to ask the lights be put on for 5 minutes per Senator for questions.

I do want to just quickly follow up on the points that Senator Durbin has raised. Many of us recently voted for a substantial increase in the food safety budget as part of the agriculture appropriations bill, but I think what GAO is saying is that as long as you have these weaknesses, as long as FDA, for example, is not focusing its resources on the greatest health risk, as long as importers are allowed to retain custody of suspect shipments, as long as shipments are not stamped "refused entry," as long as the importer has 90 days to deal with the problem rather than the 45 days that FSIS gives its shippers and importers to deal with rejected shipments, as long as those flaws exist in the system, we can add all the inspectors in the world and we are still going to have a problem. Is that correct, Mr. Dyckman?

Mr. DYCKMAN. It is correct. Without good internal controls to make sure that—for example, when a product is refused by FDA,

you could have, as you point out, as many inspectors as you want, but there is no assurance that the product is the same product that gets destroyed or reexported, you may not have accomplished anything. So you could put a lot of money into this problem and really not have substantial results. I think it has to be a coordinated, comprehensive effort. We agree that it is important to address the budgetary issues involved with food safety, but it is just as important, as you indicate, to address the internal controls. Right now, they are weak.

Senator COLLINS. I do think we need more resources and I supported the expenditure of $66 million as part of the appropriations process, but I do not want to just put more money into a broken system because more money and more inspectors, if the system is still broken, if the flaws that you have identified still exist, is not going to solve the problem.

Let me turn to a specific in that regard. Mr. Dyckman, how does the FDA's 90-day time period, which is twice the time allotted for FSIS-regulated products, make it more likely that unsafe food will be distributed in this country?

Mr. DYCKMAN. Well, it is pretty obvious that the more time an importer has and the fact that the product is in his custody, he has more time to arrange for illegal substitution.

Senator COLLINS. And it is my understanding that that is statutory. So that is something Congress has to change, is that correct?

Mr. DYCKMAN. That is correct.

Senator COLLINS. Mr. Metzger, do you see any reason, any policy or technical reason, why the time period cannot be reduced, especially considering that 75 percent of importers, I understand, would not be affected by a shortened time for redelivery?

Mr. METZGER. We have no problem with that, Senator.

Senator COLLINS. I would like to ask both Customs and the GAO, why do we allow—and I believe Senator Lieberman touched on this—why do we allow reexport of unsafe food? Why do we want it to go anywhere in the world? Why do we not order it destroyed? Mr. Oleson.

Mr. OLESON. Thank you, Senator. There are certain foods that we will not allow reexport to. They are called Class I violations, which such a thing as botulism is not supposed to be reexported, but unfortunately, there are cases where it has been.

The rationale provided to us by FDA is that some of these foods, although they do not meet U.S. standards, can meet foreign country standards or they may be able to recondition them in the foreign country. For example, if you have a salmonella-contaminated product, which is not a Class I violation, they allow reexport. If you take that product and cook it to a certain temperature, you will kill the salmonella and then it may be acceptable to eat. So it is the rationale that these products still could be reconditioned or used elsewhere is why they do not require destruction.

Senator COLLINS. I do not think the consumer would be very excited about reconditioned food.

Mr. OLESON. I cannot argue with that, either.

Mr. DYCKMAN. Particularly if it takes 2 years.

Senator COLLINS. Right. Mr. Hoglund.

Mr. HOGLUND. It is obviously a reasonable question as to why is it not destroyed, but I do not know the rationale in terms of the legislation, why an option was provided, and I also do not know if there are some commercial usages, that were taken into consideration perhaps, a reexported product can be somehow processed into some non-edible fertilizer or whatever.

Senator COLLINS. That might be a legitimate reason.

Mr. HOGLUND. The reason for reexports. I do not know if the commercial reason——

Senator COLLINS. That is the only one that I can think that might be legitimate.

Mr. Richards, I did not want you to feel slighted. My final question is for you. At an earlier Subcommittee hearing on food safety, a former FDA inspector testified that the current system of fines and penalties is nothing more than ''a slap on the wrist.'' What did GAO's review find with regard to importers' attitudes towards penalties? Did they see them as just a cost of doing business or a serious deterrent, and what kind of profits are we talking about here?

Mr. RICHARDS. Well, at nearly every port we went to, the Customs and FDA officials told us that from their experience, the importers did consider these penalties for failure to redeliver products as a cost of doing business. Regarding the types of profits that can be made, as Mr. Dyckman mentioned, we had heard in some cases that the difference between the wholesale value of the product and the cost to the importer could be as much as 10 times. That seemed consistent with what we had reported to Congress in 1992, where we also had shown some examples of differences where the wholesale value that the importer could gain from a product exceeded the penalty that was imposed for not destroying it or exporting it.

Senator COLLINS. Thank you for that information. That suggests to me another area that we need to look at as we look at the underlying laws in this area.

Senator Durbin.

Senator DURBIN. No questions.

Senator COLLINS. Thank you. I want to thank the panel for their cooperation. As was mentioned just briefly by Mr. Dyckman, we are going to be turning to the remedy stage in our next two hearings and we will welcome your suggestions and input at that time, as well. Thank you very much.

Mr. HOGLUND. Thank you.

Mr. DYCKMAN. Thank you.

Senator COLLINS. Our final witness this morning is a confidential informant and former Customs broker. We will refer to this witness today as ''Mr. Broker''. He will give the Subcommittee an insider's view of how unscrupulous importers use fraudulent and deceptive practices to circumvent food safety inspections.

For the record, I want to note that the witness has specifically requested that his face be obstructed from public view because he is still cooperating with an ongoing Federal criminal prosecution. Under the circumstances, the Subcommittee has determined that this is a reasonable request. Without objection, therefore, it is so ordered, pursuant to Subcommittee Rule No. 11. I would note for the record that the witness will testify behind an opaque screen

and no cameras will be permitted to photograph the witness from the area in front of the screen.

Pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn, so at this time, I would ask you remain seated, given the circumstances, but raise your right hand.

Do you swear that the testimony you are about to give is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. BROKER. I do.

Senator COLLINS. Thank you. "Mr. Broker," you may proceed with your testimony.

TESTIMONY OF "MR. BROKER,"[1] CONFIDENTIAL INFORMANT/ FORMER CUSTOMS BROKER

Mr. BROKER. Madam Chairman and Members of the Subcommittee, at your request, I am here today to testify about fraud and deception in the food import process. Before I begin my testimony, I would like to thank this Subcommittee for respecting my request to keep my identity protected during this hearing.

Senator COLLINS. We will just ask you to speak right into the microphone. They are a little bit sensitive, and we want to make sure we can hear you. Thank you.

Mr. BROKER. I retired in February 1998, after serving almost 20 years as a Customs broker. As a broker, I was responsible for expediting imported cargo through U.S. Customs Service and other Federal agencies. I also assisted importers with ocean, air, truck, and rail transportation, as well as their insurance needs. In addition, I advised importers on the many different agency requirements for their products and I served several hundred clients with their shipments each month.

As you stated, Madam Chairman, I recently pleaded guilty in Federal court in an ongoing Federal investigation and I am scheduled to be sentenced later this month. Consequently, I cannot discuss any details of the ongoing investigations in my case.

I am appearing here voluntary in a sense of duty to correct the mistakes of the past. Today, I will discuss some of the various techniques used by problem importers to circumvent FDA and U.S. Customs Service laws and regulations. In the interest of time, I will summarize a written statement previously submitted to this Subcommittee and will focus on the three segments of food import process: Import shipments, refused shipments, and penalties for violations of import regulations.

There are many ways in which the problem importer can avoid food safety inspections and introduce unsafe food into this country. An importer's main objective is to get their cargo to their buyers as quickly as possible, and if they are importing adulterated products, they want to avoid FDA and Customs inspection procedures. They look for ports that have lax examination procedures. Los Angeles—Long Beach and New York are two ports with the largest inbound volume and are considered the easiest ports of entry.

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[1] The prepared statement of "Mr. Broker" appears in the Appendix on page 137.

Importers and brokers know which ports have the weakest import controls and this leads to port shopping. For example, in the San Francisco area, the FDA inspectors are much tougher than Customs, but in Los Angeles, the Customs inspectors are much tougher than FDA. It is much easier to import adulterated food through these ports just because of the volume.

Imported food shipments may be inspected by the Customs Service, USDA, or FDA, and in some cases, all three agencies may inspect the same product. Customs inspectors are authorized to conduct either merchandise enforcement team, their MET exams, or CET exams, contraband enforcement team exams. Because these inspections by Customs are not focused on food safety, my experience has shown that these exams do very little to prevent adulterated food getting into the country.

When the FDA decides to inspect or sample imported food products, it will normally take place at the importer's premises. The importer is required to keep the product intact from the time it leaves the port until the FDA approves the release into U.S. commerce. Importers can take the products out of the shipping container and place them in their warehouse, but they are supposed to keep the products intact.

However, it is very easy for the importers to substitute products before FDA inspectors arrive. In some cases, the importer has from 2 to 4 weeks to prepare for FDA's arrival. This allows the problem importers to sell adulterated products and replace them with legal products from a subsequent shipment, all before the FDA inspectors arrive.

Problem importers typically import large amounts of products that will not pass FDA inspection because these have the highest profit margin. In order to get these products through FDA inspections, importers will use a banking system. This is how banking is used to avoid inspection procedures and import unsafe food into the country.

Importers will import some food items, referred to as "double clean," that will pass FDA inspection and store these items in their warehouses. When FDA arrives to inspect a shipment, the importer will provide the clean products for inspection. Once these pass inspection, the importer can reuse these items for future FDA inspections. Depending on the shelf life of the product, problem importers can use this scheme and these same products for months or even several years.

The automatic detention procedures also present problem importers with an opportunity to avoid food safety inspections. If the FDA finds imported foods that are adulterated or problematic, the FDA may place these products on automatic detention. Many importers prefer to be on automatic detention because they have control over the product. Importers prefer automatic detention because of the lab reports that are coming from private labs that are chosen by the importers rather than FDA.

Importers can submit as many samples as they like to the private labs for testing until they get a sample that will pass FDA's approval. In some cases, importers actually select the products to give the laboratory technicians for sampling. The food products

supplied by the importers may not even be from the proper shipment.

When dealing with refused shipments, even when food shipments are rejected and found to be adulterated, the current system still allows importers to sell the unsafe food. Problem importers, for example, may fill containers with trash or other items, but not the adulterated food products that the FDA has refused entry.

When the truck driver arrives to the destruction site, the inspector may only weigh the container without examining the contents of the container. The importers may stack a few boxes of the refused product in the rear of the truck, thereby losing only a fraction of the original product. There also are importers who know the Customs inspectors very well and these inspectors may just sign off on the destruction documents without doing any verification.

In addition, there are no sanctions against importers if they get caught destroying the wrong product. A truck driver can always say that he made a mistake and picked up the wrong cargo.

Customs has very few controls over the reexportation of refused shipments. Importers may present Customs with different products to be reexported than the products that were refused entry. Importers also may export products, repack them, or try to reimport them again. Importers may even try to reimport into a different port.

The penalty system used by Customs and the FDA to sanction problem importers when they try to bring unsafe food into the country is ineffective. Most penalties imposed are just written off as a cost of doing business. During my experience as a Customs broker, penalties levied by the U.S. Customs Service against problem importers do not serve as a deterrent for attempting to bring adulterated products into the United States.

In fact, virtually every time importers were sanctioned, they were able to successfully get Customs to mitigate the penalties. Importers often say it was a mistake in order to deflect the blame of any violations or may go as far as having false fire or police reports presented to Customs to show that the products were either destroyed or stolen.

This concludes my statement and I will try to answer any questions that you have.

Senator COLLINS. Thank you very much.

I know it is difficult to quantify the extent to which fraud and deception contributes to the food safety problems that we have in this country, but I want to ask you, based on your 20 years of experience as a Customs broker, how often does this happen, from your direct personal observations? Is it something that happens once a month or once a week or is it a common, everyday occurrence?

Mr. BROKER. From a small group of importers, it is every day, just every day.

Senator COLLINS. So this is a widespread problem. It occurs in ports across the country and the ports, you seem to suggest, with the most volume are particularly vulnerable and an unscrupulous importer will port shop and try to hit a time when the volume is high, is that correct?

Mr. BROKER. That is very correct. Problem importers, they look for the high-volume ports. You would not want to go to Seattle, for example, where they have very little food imports. You would want

to go to Los Angeles or New York, where the volume is so high and the inspections are so low that they virtually just pass right through.

Senator COLLINS. You mentioned in your testimony, and this is the first time I have heard this, that even when an importer is caught and a preliminary penalty is assessed, that the importer in virtually every case that you personally knew about was able to get the penalty lessened, or mitigated. How is that done? How do importers convince Customs to lower the penalty?

Mr. BROKER. In many cases, they will submit documentation that they have exported or destroyed the product. They have said they made a mistake, any number of ways.

Senator COLLINS. But is there not even a term of art among the importers called the "big mistake" letter?

Mr. BROKER. Oh, yes. There is always the "big mistake" letter.

Senator COLLINS. Could you tell us, what is the "big mistake" letter?

Mr. BROKER. Well, they start off first, well, the supplier sent me the wrong shipment, or I do not understand English, or there——

Senator COLLINS. This is done often enough that unscrupulous importers refer to it as the "big mistake" letter?

Mr. BROKER. Oh, it is just the "big mistake" letter and they just try to come up with any kind of idea they can. Many times, they have so much experience with dealing with U.S. Customs penalties, they find out which works one time and which works another and they will just continue to use that particular excuse at that time and then develop it for the next penalty. And since there is no tracking or very little tracking, I have seen probably over a dozen penalties that were over $300,000 that they were able to mitigate down to $100.

Senator COLLINS. That is an important point that you made, about the lack of tracking. So a lot of times, the inspectors do not realize that there have been problems with the importer over and over again, is that correct?

Mr. BROKER. That is very correct. Many times, the importers are tracked by company name only.

Senator COLLINS. Do the criminals in this business set up different companies under different names to try to circumvent? If they do get on what Customs referred to as the top 10 list, do they create a new corporate entity so it is harder to track them?

Mr. BROKER. Many of these companies will have three or four different names already in place. If one of these companies get into trouble, they will just shut it down and continue with the next company. I understand in Los Angeles, for about $500, you can set up a company with anyone's name as a corporation and just keep running.

Senator COLLINS. Do you know of any cases where importers have been barred from the business as part of the penalties?

Mr. BROKER. None.

Senator COLLINS. There was an issue that I meant to raise with Customs officials, and I am going to follow up, but they have developed this top 10 list of frequent violators. Why do they not just bar them from being in the business? But to your knowledge, that does not happen?

Mr. BROKER. It does not happen. I think that one of the deterrents might be they track with Social Security numbers of the people who are actually owning these companies.

Senator COLLINS. One of the weaknesses that GAO has identified for us this morning is that the importer retains custody of the shipment of food that has been questioned by the FDA. The importer selects the food to be tested by the laboratory. The importer also selects the lab. There is a lot of excess trust built into the system, it seems to me. Please comment for us on how much you think that those weaknesses contribute to the ability of an importer to evade an order by the FDA to destroy or reexport the product.

Mr. BROKER. I will say that the largest number of importers are doing business correctly, but the small majority, they can avoid it very easily. They love to go on automatic detention, if they can.

Senator COLLINS. Explain what that is for us.

Mr. BROKER. Well, if a food product—FDA finds a food product, such as rice sticks, which was mentioned this morning, it is automatic detention from Thailand because it is filthy case after case after case. FDA does not want to spend their resources running everything through their lab, so they have set up a lab or the private lab system. The importer must prove that its product is good to FDA.

Senator COLLINS. So let me understand this. In the case of, for example, rice sticks, the FDA has determined that there have been continuing problems with this product——

Mr. BROKER. Correct.

Senator COLLINS [continuing]. So it is put on an automatic watch list, essentially, an automatic detention list, and that means that the importer is required to test every shipment?

Mr. BROKER. Right, and present the lab report to FDA stating that this product is good.

Senator COLLINS. And that is the key point, is it not, that——

Mr. BROKER. Exactly.

Senator COLLINS. You have got to depend on the honesty and integrity of the importer.

Mr. BROKER. Correct.

Senator COLLINS. Do you think it would help if the FDA retained custody of the shipment and put them in a government-bonded warehouse?

Mr. BROKER. I think that is a very good idea, and have the bonded trucker also move the cargo because right there is a very large weakness in the system, because any trucker at all can move that cargo at this point.

Senator COLLINS. Thank you.

Senator Durbin.

Senator DURBIN. "Mr. Broker," in your 20 years in the industry, did you work with exporters from a variety of different countries?

Mr. BROKER. Yes.

Senator DURBIN. Did you find that there was a prevalence of fraud and deception from any particular region or country?

Mr. BROKER. In my expertise, I primarily dealt with the Orient, but I do know from other brokers throughout the country that there are problems at every port with different groups. Obviously, on the West Coast, we deal primarily with Asia.

Senator DURBIN. Is there any particular country of origin that you consider to be problematic?

Mr. BROKER. In particular, China.

Senator DURBIN. When it comes to your experience in this area, can you recall any specific examples where you were involved in shipments of adulterated food into the country? We talked here for a moment or two about seafood shipments and the like. Can you recall any in your experience?

Mr. BROKER. Well, I have seen numerous types of things, one being pickled fish that was fermented and decomposed, basically being brought in as fish sauce. Fish sauce almost always just gets a clean pass. If FDA comes in to inspect, fish sauce is cheap enough to keep around as a bank to show any inspector.

Senator DURBIN. So they bank the clean fish sauce and the other adulterated product moves through?

Mr. BROKER. Right. Shark fin is another example. Shark fin can be valued anywhere from $20 a pound to $400 a pound, depending on the condition and the species. I have seen it come in as frozen skate, which is a fish, if it is frozen. If it is dried, it can come in as just virtually anything.

Senator DURBIN. One of the things that was suggested here by the GAO was marking shipments. Is that practical? Can that be done?

Mr. BROKER. That can be done, and that will probably stop quite a bit of the problem. But for problem importers, a carton costs about $1.25 apiece and just marking the outside carton will not deter some of these people who really want to get this product onto the market.

Senator DURBIN. So the challenge is how to mark the actual food product itself, if we can.

Mr. BROKER. That is right.

Senator DURBIN. That may be quite a challenge. I am not sure.

Mr. BROKER. That is quite a challenge. I was trying to think of ways that you could do that, and it would be very difficult unless you used dye in the boxes or something.

Senator DURBIN. Have you been party to any conversations where these importers have talked about the fact that the cost of doing business may include a fine or probation, which they are willing to run that risk because of the profit involved?

Mr. BROKER. Not specifically to the cost involved, but mainly the group of the importers that I have worked with in the past, they obviously do not like the penalties, but they would much rather pay the penalty than not be able to make their sale and get that product out on the market quickly.

Senator DURBIN. In one of the previous hearings, we talked about the complicity of employees of the Food and Drug Administration and other Federal agencies in these schemes. Based on your 20 years of experience, how prevalent is that? How common is it?

Mr. BROKER. U.S. Customs, I found to be outstanding.

Senator DURBIN. In terms of——

Mr. BROKER. In the inspectors being right on the ball and not looking for any additional profits, personal gain.

Senator DURBIN. Honest?

Mr. BROKER. Very honest. FDA, I think I have seen so many opportunities for them out there that that is where the problem has been.

Senator DURBIN. We talked earlier, I do not know if you were here, when the panel testified about the number of inspectors at FDA as opposed to some other Federal agencies. Is this common knowledge, that the FDA inspectors have a larger workload than some other agencies that are responsible for this inspection?

Mr. BROKER. Absolutely. If you have a problem shipment and you try calling FDA to discuss it, you are very lucky to get a phone call back because they are just overloaded, or trying to get an inspector out. We have had releases—it is basically a standard procedure that if a FDA inspector has been notified and in 2 weeks he still has not been able to get to the inspection site, they will release the cargo without inspection.

Senator DURBIN. One of the other things that was discussed was whether or not there is sufficient inspection, for example, that the Customs Service does get inside a box to determine what the contents actually are as opposed to the manifest or what is written on the outside of the box. What has been your experience in that regard?

Mr. BROKER. Well, Customs inspectors, taking, as an example, the CET teams, they are looking for drugs. If it is not a drug, they do not care. The box just moves. MET teams are more thorough, but if the invoice says that it is noodles and a MET team inspector goes up and looks at rice sticks and it says noodles on the box and it looks like a noodle, it is a noodle.

Senator DURBIN. So in terms of breaking open the package, taking a close look at the contents, is that a rare occurrence?

Mr. BROKER. It is a fairly rare occurrence.

Senator DURBIN. Thank you very much for your testimony.

Senator COLLINS. Thank you very much. I want to thank you for your testimony today and for providing assistance to the Subcommittee staff as we attempt to get a handle on this.

I think perhaps the most shocking statement that you made today was the fact that there was in one case a $300,000 penalty——

Mr. BROKER. Several cases.

Senator COLLINS [continuing]. Several cases where that was lowered, ended up being only a $100 fine.

Mr. BROKER. Correct.

Senator COLLINS. I just wanted to make sure I heard that correctly.

Mr. BROKER. That is correct.

Senator COLLINS. Thank you very much for your participation.

I would ask that everyone remain seated for just one moment prior to my adjourning the hearing so that "Mr. Broker" may exit the room. And again, I would remind any cameras, if there are any here, to please refrain from taking any pictures while the Capitol Hill Police escort the witness from the hearing room.

Senator COLLINS. I want to thank Senator Durbin for his participation in the hearing today. He has been a real leader in the food safety area and I know we are going to continue to work closely on this as we turn to the next stage of this investigation.

Today's hearing, which focused on fraud and deception in the food import process, highlighted a very disturbing problem, and that is that unsafe food contaminated with dangerous pathogens is distributed in this country, in part because of weak import controls, poor coordination among Federal agencies, and low penalties for violating food safety regulations. The chances of the FDA catching contaminated products through inspections at the border, we know is very low, given the low number of inspections, but what is more disturbing to me is the fact that even when a shipment has been detained, that it so frequently makes its way into the American marketplace. That is simply unacceptable and we have to have a better system in place.

As I mentioned in my opening statement, this hearing is the third in a series of hearings. We will now turn to the remedy stage of the investigation process. We will hold 2 more days of hearings on September 24 and 25. The first day will give Members of Congress and Executive Branch officials the opportunity to provide recommendations for improving our Nation's food import system. On the second day, the Subcommittee will hear from a wide variety of private sector groups.

With that completion of our hearings, I look forward to working in the next few months with my colleagues in the Congress as well as the Executive Branch and the private sector to develop some legislation to really address this issue.

Again, I want to thank all of our witnesses today for their testimony. We will keep the hearing record open for an additional 10 days in case Members have any additional questions.

I also want to thank my very capable PSI staff for their usual excellent job in this area.

The Subcommittee is now adjourned.

[Whereupon, at 11:25 a.m., the Subcommittee was adjourned.]

IMPROVING THE SAFETY OF FOOD IMPORTS—PART IV

THURSDAY, SEPTEMBER 24, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:06 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins, Levin, Lieberman, and Durbin.

Staff present: Timothy J. Shea, Chief Counsel/Staff Director; Mary D. Robertson, Chief Clerk; Christopher A. Ford, Senior Counsel; Mary G. Mitschow, Counsel, Don Mullinax, Chief Investigator; Kirk E. Walder, Investigator, Stephanie A. Smith, Investigator; Lindsey E. Ledwin, Staff Assistant; Pamela Marple, Minority Chief Counsel; Beth Stein, Counsel to the Minority; Brian Benczkowski (Senator Domenici); Michael Loesch (Senator Cochran); Felicia Knight (Senator Collins); Nanci Langley (Senator Akaka); Marianne Upton (Senator Durbin); Lynn Kimmerly (Senator Cleland; Kevin Landy (Senator Lieberman); Jeffrey Goff (Senator Cochran); Pam Maku (Senator Specter); Tyler Wegmeyer (Senator Cochran); and Antigone Popamianos (Senator Levin).

OPENING STATEMENT OF CHAIRMAN COLLINS

Senator COLLINS. The Subcommittee will please come to order. Good morning. I want to apologize for the late start today. We are unfortunately in the midst of a series of votes, so we may have to come and go during this hearing, but we will try to keep the recesses and interruptions as brief as possible.

In June 1997, the Permanent Subcommittee on Investigations began an in-depth investigation into the safety of imported food, with particular focus on imported fruit and vegetables. Over the last 14 months, Subcommittee investigators have consulted with representatives from 27 industry, consumer, and science-based organizations, as well as with officials from the General Accounting Office and seven Executive Branch agencies. We have reviewed, as part of our investigation, thousands of pages of documents, conducted in-depth interviews with 25 experts, and heard testimony presented by 13 witnesses at three previous Subcommittee hearings.

Our prior hearings have covered a great deal of ground. In our first hearing we discussed the findings of a General Accounting Office study examining the prevalence of foodborne illnesses and ex-

posing serious deficiencies in Federal efforts to ensure the safety of imported food. In our second hearing we undertook a case study of dangerous microorganisms carried into the United States on imported fruit—raspberries from Guatemala. In our third hearing we examined how weak controls exploited by unscrupulous importers can completely undermine the food safety net that is intended to protect American consumers.

These issues are literally life-and-death matters for many Americans. As we learned at our previous hearings, the very old, the very young, and the very ill are most at risk for foodborne illnesses that cause as many as 9,000 deaths each year in our country.

In today's global economy, we import a huge volume of food from all over the world. In 1996, for example, we imported some $7.2 billion worth of fruit and vegetables alone from at least 90 different countries. Most of this food, I want to emphasize, is perfectly safe and provides Americans with an enriched diet and the year-round variety that we enjoy. But far too often, contaminated products, from domestic as well as imported sources, reach the tables of American families, causing more than 80 million cases of foodborne illnesses each year.

This investigation has revealed much about the food we import into this country and how our government attempts to protect Americans from unsafe food. Over the course of the past several months, we have learned that Americans are eating more and more food produced in foreign nations. Shipments of imported food have doubled over the past 5 years, and that amount will only continue to grow.

Foodborne illnesses have a significant impact on public health as well as a substantial economic impact. Maintaining the food safety net for imported food is an increasingly complex task, made more complicated by previously unknown foodborne pathogens like *Cyclospora*.

Since contamination of imported food can occur at many different places from the farm to the table, the ability to trace back outbreaks of foodborne illnesses to the source of contamination is a complex process that requires a coordinated effort among the Federal Government, State agencies, and local agencies.

Because some imported food can be contaminated by organisms that cannot be detected by visual inspection or laboratory tests, placing additional Federal inspectors at ports of entry alone is not sufficient to protect Americans from unsafe food imports.

Federal agencies have not effectively targeted their resources on imported foods posing the greatest risks. In the words of the GAO, Federal efforts are "inconsistent and unreliable." Weaknesses in FDA import controls, specifically the ability of importers to control the food shipments from the port to the point of distribution, allow unsafe food to enter the American marketplace.

The civil penalties imposed on importers who violate food safety regulations are so low that they are often considered as simply a cost of doing business. And, finally, the enforcement of existing criminal laws provides little deterrence for unscrupulous importers.

These are some of the Subcommittee's preliminary findings, based on our hearings and investigation to date. Today, based on these and related findings, we will take the next step in our inves-

tigation by hearing recommendations from a wide range of witnesses on how we can correct the flaws in the current system, which I have just enumerated, and what changes need to be made in Federal practices, regulations and laws.

My goals are to help ensure that food safety programs are effectively managed; that existing resources are focused on those imports posing the greatest risk of harm to Americans, and that deficiencies in the underlying regulations and laws are remedied.

Ensuring the safety of food imported into the United States, we have learned, is a very difficult and complex task. Countries have different food production and handling practices, regulations and standards. Different regions of the world also have different indigenous microorganisms and other pathogens to which the local population—but often not American consumers—may be immune.

As long as food imports continue to grow, these variations will continue to have a significant impact on the safety of our food imports. Moreover, new threats are developing all the time. Some harmful organisms, such as *Cyclospora,* cannot be detected through visual inspections or even through lab tests, and they have emerged as dangerous to Americans only within the past few years.

A mosaic of Federal laws and regulations, including at least 35 Federal statutes, govern this process. In addition, each of our 50 States has its own food safety and inspection system, making an important contribution to the Nation's food safety net.

Today and tomorrow, our hearings will focus on how the Congress, the administration, State and local authorities, and the private sector can work together to strengthen our food import system. As we consider granting new authority and allocating new resources, we must be sure that current laws are vigorously enforced and that existing resources are efficiently spent. More money alone will not fix a broken system.

We will hear today from two panels of witnesses, foremost among them my colleagues Senator Paul Coverdell of Georgia, Senator Barbara Mikulski of Maryland, and Senator Ted Kennedy of Massachusetts. Each of these Senators has a strong interest in food safety issues, and I look forward to hearing their testimony and recommendations. I also suspect that each of them is still on the floor voting, but we may be having them join us shortly. I also see from the witness table that Senator Harkin, who has been a leader in this area, is also expected to join us this morning.

Our second panel of witnesses includes senior Federal officials from the primary Executive Branch agencies with responsibility for the safety of imported food, including representatives of the FDA, the Customs Service, and the Food Safety and Inspection Service of the Department of Agriculture. They will be joined by a member of the Food Safety Committee of the National Academy of Sciences.

We look forward to hearing from all of our witnesses today, and to exploring ways to improve our food safety system. I would note that tomorrow's hearing will feature witnesses representing industry and consumer groups, and a wide variety of organizations will be represented.

It is my understanding from the staff that Senator Kennedy is on his way, so we will just be in recess for a few moments awaiting the appearance of my colleagues.

[Recess.]

Senator COLLINS. We have now been joined by the distinguished Senator from Connecticut, and I will call upon him for any opening comments that he might have.

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Well, thanks, Sue, very much. Madam Chairman, I am very pleased that once again you have put together an excellent hearing with a very good group of witnesses. I gather that we may hear at some point from our colleagues, whose spirits are with us, so *in absentia* we will thank them for their dedication to this important issue, the safety of our food supply.

In addition to the Senators testifying today, two of our colleagues on the Subcommittee have also introduced legislation relating to food safety. Although all of these bills, I think, take different approaches, they do not take contradictory approaches, and I think they are all constructive pieces of legislation that we will want to consider.

The safety of our food supply is an issue which should unite everyone in this country and even in this legislative body of ours. Our common enemies here are unseen pathogens which can strike thousands of Americans and make them ill. There are unscrupulous importers, enemies of ours, who knowingly risk grievous harm to others for an easy buck. And, finally, the common enemy we have here is our own failure to be vigilant.

I think that the hearings that you have organized and have presided over, Madam Chair, have contributed substantially on each of these fronts, and now to our understanding that there is a real problem out there that affects the well-being, the health of millions of our fellow Americans, indeed of our own families, and now it is time to move to solutions. You will allow me, I hope, the pun of saying notwithstanding what we have learned previously, I am hungering for solutions.

And I look forward in that spirit to the testimony of our witnesses today, and thank you again for your leadership.

Senator COLLINS. Thanks very much, Senator. I see that we have begun yet another vote. I suspect that the Senators who will be testifying will wait and vote first, so I am going to do likewise, so we will suspend the hearing for about 10 minutes.

[Recess.]

Senator COLLINS. The Subcommittee will be in order.

We are very honored this morning to have a distinguished group of our Senate colleagues with us. They each have a keen interest and much expertise in the area of food safety.

We are going to begin with the distinguished Senator from Georgia, Paul Coverdell, who is the Chairman of the Agriculture Subcommittee on Marketing, Inspection and Product Promotion. He is a leader in the Senate on issues related to food safety and imports, and earlier this year introduced his own legislation, which innovatively increases and targets food safety research and education programs. If you would, please proceed, Senator.

TESTIMONY OF HON. PAUL COVERDELL, A U.S. SENATOR FROM THE STATE OF GEORGIA

Senator COVERDELL. Thank you, Madam Chairman. I am most pleased to have the opportunity to testify before the Permanent Subcommittee on Investigations to discuss this issue of great importance, food safety. I would like to thank Senator Collins for holding these hearings on the safety of imported food and bringing this issue the proper attention it deserves, and I am pleased to be here today with my colleagues, Senators Kennedy and Mikulski.

This is an issue in which I have taken special interest as Chairman of the Senate Agriculture Subcommittee with jurisdiction over food safety issues, and as Foreign Relations Subcommittee Chairman for the Western Hemisphere. I have long been interested in maintaining our high standards of food safety while we have become increasingly active with our hemispheric trading partners, particularly in fruit and vegetables. With this growth in imports, I have advocated a commensurate growth in resources necessary to understand and address the challenges we face in maintaining our food safety standards.

The public is also becoming concerned with the safety of their food. Over the past year there have been increased reports of foodborne illnesses. GAO reported in May 1996 up to 81 million cases of foodborne illnesses, what we just talked about, Madam Chairman, and 9,100 deaths occur each year in the United States, and this is certainly cause for concern. I believe that we should take a thoughtful, well-researched approach to addressing the problem.

There have been well-publicized cases of food safety problems, to be sure. Recently both children and adults became ill with Hepatitis A from contaminated strawberries distributed to schools through the USDA school lunch program. There was an outbreak of *E. coli* 0157H7 which prompted the massive Hudson beef recall, and recent problems with this same pathogen in my State, where over 20 school children were stricken and hospitalized with this deadly ailment. We have seen problems in products as diverse as ground beef and apple juice.

I believe that protecting our Nation's food supply should be a high priority for Congress and this administration. We can do better, and we will, if we set the right course. With technology advancing at lightning pace, there is no excuse not to develop and significantly improve our food safety for the 21st century.

This is one area where food producers may be ahead of the processors, albeit with their government regulators, in technology, but this can certainly be changed with the proper focus. We are increasingly becoming a global economy. Agricultural trade is on the rise and is of permanent economic importance to American agricultural producers.

This places more emphasis, of course, on our hemispheric trade of perishables such as fruit and vegetables. Farmers in foreign countries, particularly in Central and South America, can harvest, pack and ship to the United States in short order, with their products sometimes on the grocery shelves as quickly as 24 hours later.

These new food supply options have been of great benefit to consumers in the country, allowing a wider availability of products

throughout the year. I would imagine that the Chairman's constituents are often the beneficiaries of these new suppliers in times where domestic products just aren't available.

So these systems are very important to our food supply, but they are not without new challenges of food safety. These challenges have prompted various legislative responses. All, I believe, are well-intentioned. There are proposals currently being considered which give Federal agencies, specifically for today's business, the Food and Drug Administration, FDA, additional regulatory authority in erecting more barriers before foods can be imported into the United States.

I believe we should be cautious and thoughtful before enacting such legislation because it will likely have complex ramifications without proof that it will actually improve food safety. I am not opposed to this approach, but I do think there are many questions to be answered before granting such broad authority to FDA.

Before we do this for any agency, we need to ensure that the current systems in place are actually working and that we are not overlooking obvious holes in them. I was extremely concerned with how our Federal agencies are operating after reviewing the April 1998 General Accounting Office report entitled "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable."

The GAO report stated that the Food and Drug Administration's procedures for ensuring that unsafe imported foods do not reach U.S. consumers are vulnerable to abuse by unscrupulous importers. This type of abuse must be stopped. There needs to be a system in place which guarantees when the FDA discovers imported contaminated food, it is either reexported or destroyed in a timely fashion.

In addition, the GAO report found that the Food Safety and Inspection Service and the Food and Drug Administration are not deploying their inspection resources to maximum advantage. The GAO report also showed problems with importers port-shopping, and the FDA's inability to properly control the selection of the samples tested by private laboratories or to certify acceptable private laboratories.

These are just a handful of the problems cited by the GAO which Congress and this administration need to address. From my own experience, I saw produce sit on the tarmac at Miami Airport for hours before being inspected, I might add, at horrendous temperatures. This can't be good for the produce or the consumer.

Further, I saw the sheer volume of products coming to the United States from other nations, and quickly recognized that technology was the key to this food safety. Simple manpower, while helpful, will not fully address our food safety needs. We need more advanced and scientific solutions to these problems. There have been positive steps taken by the FDA in this regard. They have often acted professionally and constructively in working with other nations to address food safety problems.

My personal experience has been with the Guatemala raspberry project. The FDA and Center for Disease Control and Prevention have done an excellent job in working with the Guatemalan Government and the Guatemala Berry Commission to develop what

will likely be a food safety model for other nations in the hemisphere. Upon CDC's realization of the problems with *Cyclospora* associated with Guatemalan raspberries, they joined the Guatemalan producers and the FDA in working tirelessly to develop a safer system of production.

The result was the model plan of excellence. This plan was designed in an effort to mitigate all potential hazards in the production of these raspberries, and is based on our Hazard Analysis Critical Control Point system. It has undergone the highest level of scrutiny by the Guatemalan Government and the FDA, and is expected to be a breakthrough system for the raspberry industry and potentially others like it.

I have personally toured a farm that qualifies under the model plan of excellence, and I must say that I was most impressed by its level of sophistication and by the dedication of those producers working to develop it. Impressive also was the commitment to food safety of those industry and government officials I met in Guatemala. It was encouraging to see that our government agencies could pay such an active role in addressing, at its root, not a problem affecting a multitude of consumers.

I will not belabor the model plan of excellence, which I hope will be a successful program for the advancement of food safety, but I do hope that the Chairman will have an opportunity, either through an inquiry or testimony, to hear more about this unique project from the Food Marketing Institute, who I understand has been instrumental in working with the growers and FDA in its development.

My point in mentioning this project in Guatemala is to show that cooperation can exist between parties interested in improving food safety, and it is going to be necessary for this to occur if we want to better understand the complexities of the new food sources. I must say, as an aside, that even to the level of the President of the country there was a commitment to engage this issue and resolve it.

In summary, I believe that we need to place a greater emphasis on food safety consumer education, research, and prevention efforts in order to maintain our safe food supply. It is highly unlikely that Federal agencies can ever ensure that foods are 100 percent safe for consumers, so it is important for consumers to be well-prepared and educated on how to prevent potential risk in their food supply.

Earlier this year I introduced a comprehensive food safety proposal, the Food Research, Education, Safety and Health Act of 1998, S. 2025, also known as the FRESH Act, which will provide additional tools necessary to improve our overall food safety. This legislation focuses on consumer education, research and prevention efforts.

It authorizes consumer education block grants to the States; establishes a Food Safety Council in which the administration seems to be interested with their recent announcement to establish such a group; promotes risk assessments for animals, fruit and vegetables; and encourages a variety of other activities which I feel are aimed at improving food safety. In deference to the Chairman's time and intent this morning, I will not discuss the food safety bill, but will look forward to working with Members of the Sub-

committee and of this panel to develop a proper food safety initiative.

I do hope that some of my comments and experiences have been helpful in outlining the approach that I would like to see Congress take—studied and targeted. I look forward to reviewing Senator Mikulski's proposal and continuing to work with the Chairman and her staff on this most important issue. Again, Madam Chairman, thank you for allowing me to testify and for your leadership on this issue.

Senator COLLINS. Thank you very much, Senator, for sharing with us your extensive experience and insights into this area. I know that we are running behind schedule, so if any of the Senators before us have to leave, we will submit questions for the record.[1]

Senator COVERDELL. Thank you.

Senator COLLINS. I am now very pleased to call upon my New England neighbor, Senator Kennedy, who is the Ranking Democrat on the Committee on Labor and Human Resources, which has jurisdiction over many of the food safety issues. Senator Kennedy, welcome.

Senator KENNEDY. Well, thank you very much, Madam Chairman. Since the principal sponsor of the legislation, which I am interested in, is co-sponsored by my friend and mutual colleague, Senator Mikulski, I would be glad to yield. And then if she possibly leaves out one possible point, which I doubt that she will, I will just make a very brief comment and then submit my full statement. But perhaps we could recognize her first, and then I will make a brief comment after.

Senator COLLINS. I would be happy to.

Senator Mikulski, it is a great honor to welcome you to the Committee. I know you have had a longstanding interest in this area and have been a real leader, and I have enjoyed our discussions on this issue, and look forward to working with you and hearing your testimony.

TESTIMONY OF HON. BARBARA MIKULSKI,[2] A U.S. SENATOR FROM THE STATE OF MARYLAND

Senator MIKULSKI. Well, thank you very much, Senator Collins, and in the interest of time, because I know we got a late start as well, I would like to ask unanimous consent that my entire statement be placed in the record.

Senator COLLINS. It will be.

Senator MIKULSKI. And I am very delighted to be here with you and Senator Lieberman this morning, and would like to congratulate the Permanent Subcommittee on Investigations for looking into this issue.

Far too often the American people have been scared because they pick up the paper and read about yet one more outbreak of foodborne illness: The killer raspberry, the suspicious cantaloupe, the juice that was unpasteurized that resulted in severe illness in children. And what we need to do is not only manage the panic and

[1] Questions for the record appear in the Appendix on pages 466-482.
[2] The prepared statement of Senator Mikulski appears in the Appendix on page 142.

manage the fear, but do that by coming up with really sensible solutions.

I believe your previous hearings have really laid the groundwork on what the nature of the problem is, in taking it out of headlines and bringing it into Congress to look at how we can protect the public health of the American people. I congratulate you on this, and in my own way, working with Senator Kennedy, have tried to come up with, again, a sensible solution.

We agree what our principles are that every person should have confidence that their food is fit to eat. We also need to be confident that imported food is as safe as food produced in the United States of America.

We also recognize that our food supply has gone global, so we need to have global food safety, yet recognizing the national sovereignty of other nations. The statistics speak for themselves. We know that now over 40 percent of our food, particularly in fruit and vegetables, is imported. Farm produce that crosses our borders also must be safe.

Now, we have rules on imported products where we guarantee safety. Cars can't be imported to the United States unless they meet safety requirements. Prescription drugs can't come into the United States of America unless they meet FDA regulations. So you shouldn't be able to import food that isn't up to U.S. standards, either, because those safety standards are absolutely crucial.

You could go your whole life and never drive a car. You might only take a prescription drug for emergency situations. Yet you eat food every single day, which is why we need to be both vigilant and effective.

We can go over those problems, and I know Senator Coverdell and others have indicated what they were: The imported strawberries that infected Michigan children with Hepatitis A; the whole issue around vegetables and juices that resulted in these illnesses. I know you have documented that as many as 81 million Americans become ill each year and over 9,000 die as a result of food-related illnesses.

Now, some are problems in our own country, where people don't follow the basic practices of public health, personal hygiene, and basic sanitation. But at the same time, what is now happening is that, because of the all-year-round growing cycle around the world, more and more food is coming into this country.

What is the FDA doing? Well, their system has been documented by GAO and by their own declaration, is they do it at the dock, looking at individual shipments. Well, colleagues, you can't ensure our food safety one raspberry at a time, and that is essentially what it is: One dock, one pier, one port, one raspberry at a time. So we need to look for other solutions.

I have been fortunate enough to be able to be in the State of Maryland where we have the Johns Hopkins School of Public Health, and they have instilled in me the concept of public health. What is public health? One, epidemiology; know where the problems are; go to the root cause. So if you treat malaria, you don't do it by slapping it on your arm; you go to the swamp. Also, the issue is prevention. Look at the systemic issues and then deal with it.

Our food safety bill, that is sponsored by Senator Kennedy and me really follows a public health model. What it does is give the FDA authority to ban imported food from the United States if it was grown or handled under unsanitary conditions that do not meet the same as U.S. level of protection. The bill allows the FDA to ban foods from places that deny the FDA the right to inspect their production processes, and the Secretary of Health would develop the plan for the implementation.

What this bill actually does is improve the imported food processes of the FDA, and it aims at preventing foodborne illness of all imported food. It places emphasis on the underlying food system at the food source, which is ultimately a more preventive way of addressing it. By allowing FDA to consider a nation's food safety system and make recommendations in compliance with our rules and World Health Organization practices, we can deal with this.

There are several things that I want to be careful that we know it does not do. It does not violate any nation's sovereignty. That is not our business. It does not shut our borders or immediately deny food entry. It doesn't require inspections or access without consent of a nation. In fact, it doesn't create any of those new inspection authority.

But it does enable the FDA to evaluate, working with the other nations, what their food supply is. What this bill will do is really significant. It will provide FDA with a more effective enforcement tool, the ability to use its resources more effectively, and also, by looking at what we can do with other countries—like the Guatemala situation, the way Senator Coverdell just talked about his work with them—particularly Latin American and Central American countries.

We will not only—by looking at the systemic issues, bringing to bear and encouraging public health practices in compliance with their own standards and World Health Organization basic public health recommendations—ensure the safety of our food supply, but we will help a nation upgrade its food supply for its own internal consumption. I think that's pretty good because this is working with other nations and being able to do this. And if these steps are not taken, then the penalty will be that they can't bring their food to the United States of America.

Let me conclude by saying this: Yesterday the Labor and Human Resources Committee voted to approve Dr. Jane Henney's nomination as FDA Commissioner. Hopefully the Senate will confirm Dr. Henney and we will have a permanent Commissioner of FDA.

Over 4 years ago I joined with another member of your party, Senator Nancy Kassebaum, and we embarked upon a historic effort, which was to modernize our FDA in terms of its pharmaceutical drugs. We sought then something called the sensible center, where we pulled together the best ideas and the best practices, checked our party hats at the door, and worked in the national interest. America is better off because of that effort, and it is one of my proudest accomplishments.

I look forward to doing the same thing with you, to be able to work now; if we can't get a hearing this time before we adjourn, and action, that between now and the time we reconvene, perhaps Members of your Subcommittee and we could meet with you and

Dr. Henney, get a framework, and hopefully that by the beginning of the next session we will be able to introduce legislation that represents the sensible center, protects Americans' food supply, recognizes that we want a cash crop coming from overseas. I would rather have raspberries than some of the other stuff they are being exporting to this country. And we will really help their own country and help them, as well.

Thank you.

Senator COLLINS. Thank you very much, Senator. Don't take this as a political endorsement, but I do very much look forward to working with you on legislation that we can introduce in the next Congress.

Senator MIKULSKI. Oh, I won't take it as a political endorsement, but I hope others will. [Laughter.]

Senator COLLINS. Thank you.

Senator Kennedy.

TESTIMONY OF HON. EDWARD KENNEDY,[1] A U.S. SENATOR FROM THE STATE OF MASSACHUSETTS

Senator KENNEDY. Thank you, Madam Chair, and I would like to submit my statement in the record.

I want to thank you, Madam Chair, for the good work that you have been doing and this Subcommittee has been doing to try and make our food supply safer. I think it has been enormously important, and many of us have been following the hearings that you have had.

I commend you for the range of witnesses that you have today and tomorrow. You really have lucked out to get the best in the country. I know we have got many behind us here who can speak with enormous competency about this issue, so I will be very brief.

I want to acknowledge the leadership of my friend and colleague Senator Mikulski on this issue, with the introduction of the legislation and her constant pursuit of a safer food supply.

My friend Senator Harkin, who has been really an outstanding leader, was the offeror of the amendment which is in the conference now in terms of increasing food safety funding, so that we are going to be able to take immediate steps prior to the time that we leave this year, to make sure that we are going to bring the resources at the FDA to a more legitimate level to provide for the kinds of protection Americans expect. I know he will outline the reasons for that, as we all heard him on the floor convincingly, and the overwhelming vote, bipartisan, to try and give the kinds of resources to the President's Food Safety initiative.

We are all mindful of the additional kinds of challenges that we have given to the FDA in recent times. We have given them not only the new legislation of last year. We have given them increased responsibilities in terms of food safety. We gave them natural food legislation, many other different responsibilities, without giving them additional kinds of resources, so they have been very pressed in recent times.

But I would suggest, as has been mentioned here, that we are seeing the dramatic increase in imports that all of us understand

[1] The prepared statement of Senator Kennedy appears in the Appendix on page 144.

because of the changed kind of eating habits that have taken place here in the United States. At the same time, we must also note the fact, as Senator Mikulski has pointed out, that we are only inspecting a very, very small, 1.7 or less than 2 percent of all the products that come here.

But let me just give special urgency to not only the GAO report but the Center for Disease Control report. It really puts into perspective the fact that we are not just talking about the quantity that is coming in—but it also is the change in these foodborne diseases which are coming in. For half of the illnesses and sicknesses from foodborne diseases, we don't even know their cause.

We have seen these dramatic changes that are taking place in terms of the food that is coming into these United States, that is providing a very significant and important public health risk. So it isn't just the flow line in terms of the amount and the changed kind of interest of the American consumer, but it is the various products themselves that are coming in here, into a population that is changing, that is becoming more vulnerable to some of these foodborne diseases. Populations are coming here to the United States, are coming from different kinds of societies that have different kinds of challenges that are related to the various pathogens themselves.

The resistance of various bacteria to some of the prescription drugs we have is a matter of enormous importance. In many respects, this hearing, I think, and this legislation, are of monumental importance. All American families assume that when they go to that supermarket, it is going to be safe and secure for themselves, and particularly for their children.

I think we are at the cusp of a very, very important and, I think, dangerous period, where we are going to have to make sure, if we are going to insist that our food supply is going to be the safest, that we are going to take certain kinds of steps at the beginning. Senator Coverdell has got some ideas, but I basically believe that what we have to do is go back and look, give the FDA the authority, as Senator Mikulski has outlined, to work with other countries to ensure that they have adequate systems in place.

It is in the countries' interest. It may take some time before they believe it, but after they get that stamp of approval, it is going to expand their opportunities for marketing. And it is also really in the interest of the United States. I will just end with this.

I know that there are certain interest groups that want to resist this approach—for a variety of different reasons that you will hear about. But the fact is, when they get bad strawberries that come from Guatemala, people stop eating strawberries in Massachusetts. If they get bad raspberries, people stop eating them. If they know that these are going to have the good stamp of approval, the opportunity for expansion of trade for these countries, I think, expands dramatically. We have figures and statistics that demonstrate it. I won't get into that, but I think it is pretty self-evident.

So I would hope as you go through, Madam Chair, that you will give particular emphasis to the kinds of recommendations and the kind of concerns that are reflected in the Center for Disease Control's report, because I think that they have outlined the real serious challenge that we are going to be facing for a safe food supply.

I believe that the legislation that Senator Mikulski and others have supported, that I know that you are interested in and reviewing carefully, will at least give us the opportunity to make a very, very important contribution in giving the American families the assurances of a safe food supply.

And I thank the Chair.

Senator COLLINS. Thank you very much, Senator Kennedy. We very much appreciate your taking the time to appear this morning.

I am now pleased to call on Senator Tom Harkin. Senator Harkin has been very helpful to this Subcommittee on a wide variety of issues. I think you testified at the very first hearing that I held on Medicare fraud. And I am pleased to welcome you today in your position as Ranking Minority Member of the Senate Agriculture Committee, and as a Member of the Appropriations Committee. You may proceed, Senator.

TESTIMONY OF HON. TOM HARKIN,[1] A U.S. SENATOR FROM THE STATE OF IOWA

Senator HARKIN. Thank you, Madam Chair. I am beginning to feel like a regular at this Subcommittee, a witness or something like that.

But I do applaud you because you are using your Subcommittee to look into areas in your investigative role, and to bring to light concerns that affect people around this country, and I applaud you for that, Madam Chair. You are doing a really good job with this Subcommittee in a variety of areas, and this is just another one where as I heard Senator Kennedy, Senator Mikulski, and Senator Coverdell say before I got here, this is a tremendously growing concern among the American populace.

I share with you a poll that came out in the *Des Moines Register* just 2 days ago, and the headline is "Food Safety Is Consumers' Top Concern." Listen to this:

"When asked to rate the importance of food safety as a public issue, 89 percent of the consumers surveyed rated it as very important," and it beat out crime prevention at 82 percent. They are more concerned about the safety of food than they were about crime now.

Well, they have read the stories. Last year we had the largest recall of ground beef in our history. In June we had 12 outbreaks from contaminated food, one of those being an *E. coli* 0157H7 outbreak. One person died of that, that we know of. And so people are getting very, very concerned about the safety of their foods.

So I commend you for having this hearing, and bringing this to the attention of the public and of the Senate. I might just point out that this is the only Subcommittee that has had a hearing on this issue. The Agriculture Committee has not. The Labor Subcommittee on Health has not. We have over a dozen bills pending in the Senate right now on the food safety issue, and this is the only Subcommittee that has had a hearing on it. So I commend you, Madam Chair, for doing this.

I would say that I have been involved in this area for a long time in terms of meat and poultry inspections, and how we ensure the

[1] The prepared statement of Senator Harkin appears in the Appendix on page 145.

safety of our meat supply in this country. Last year I introduced a bill, S. 1264, called the Food Safety Enforcement Enhancement Act. It gives the Secretary of Agriculture more authority, both to recall and to levy civil fines.

Some in the industry have said we don't need that right now. They will recall voluntarily. Right now, if there is an outbreak, the Secretary has no authority to recall. He doesn't have it. Now voluntarily the companies can do it, but the Secretary can't, and I just want to give him that authority to recall contaminated meat any time he finds it.

The second provision is to impose civil fines. The industry says, "Well, the Secretary can already close down a plant," shut it down. As Secretary Glickman said, that is the "atom bomb" approach. There ought to be something less than that, because if you shut down a plant, you put workers out of work, and they may not have been responsible for the problem in the first place.

Sometimes under the new HACCP procedures that we have now, a problem could have been inadvertent, but you need to levy a civil fine so that it sends a signal to others to clean up their act. If we can have civil fines levied if you mistreat a circus animal, if you can levy a fine for violation of the Pecan Promotion Act, but the Secretary cannot levy a fine if you produce contaminated meat, that just doesn't make sense. So hopefully we can get something done on this to give the Secretary a little bit more authority.

Senator Kennedy mentioned the Food Safety Initiative funding on the ag appropriations bill, the amendment we got through. The Senate vote was 65 to 34. The administration had asked for $96 million. We were able to restore $66 million. Because of PAYGO, we had to find offsets for it. We did find for offsets $66 million for the food safety initiative of this administration.

That funding is in conference right now, and I would like to be able to sit here today and tell you it is all secure, but I am not certain about that. So I ask all of you on both sides of the aisle, if you have any contacts in the House, to please reach across to the other side on the ag appropriations conference and ask them to hold that $66 million that we have for the food safety initiative. It is two-thirds of what the administration asked for, but I just hope that we can keep it. And I am not certain that we can, but we will fight for it.

Last, Madam Chair, I share with you your concern over fresh fruit and vegetables. As others have said and as you know, more and more people are eating more fresh fruit and vegetables because of increasing imports. We can have fresh raspberries in the middle of the winter, and strawberries, as Senator Kennedy spoke about.

We really have been lax in setting up a regime to ensure the cleanliness and the lack of contaminants on the fresh fruit and vegetables that come into this country. I don't know that I have an ironclad answer for you, but I do believe that two elements must be involved here.

First, the FDA has to be given more authority in this area. As you know, FDA has implemented standards for dairy and canned foods. That was some time ago. They recently mandated a new HACCP system for seafood. They are now working towards similar

systems for juices and sprouts. And, they are working with industry for some voluntary guidelines for other types of produce.

Now, these guidelines are voluntary. They are not quite all we need, but at least they are moving in the right direction, and we need to figure out how we can give FDA the same kind of authority for fruit and the vegetables, especially those that come into this country, as we are hoping that the Secretary of Agriculture would have in meat and poultry products.

When I talk to consumers, while the polls all indicate that there is a great concern about meat because that has been in the news and because of the recall last year, I am finding more and more people concerned about the produce they buy and where it comes from, and whether it is clean and healthy and wholesome. So we need to set up a regime to have imported produce meet certain guidelines for cleanliness and for lack of contamination as we do for our own that are grown in this country.

Last, on the CDC, I just met with the new director of the Center for Disease Control and Prevention yesterday—I think he is taking over in about a week—and again, we need to figure out how we give more authority. I talked to him specifically about this. He said, "What do you have on your mind?" I said, "Food safety."

And CDC has done a good job. They do a really good job in tracking things down. If there is an outbreak, they can track it. They are pretty darn good at that. What they need to be involved in more is prevention, and what they can do to prevent contaminants from entering foods in the first place.

Again, I don't have an ironclad answer for you, but I look forward to working with you, Madam Chair, and other Members of the Subcommittee, to increase both the authority and power of the FDA, but also to give more guidance and direction to the CDC for getting up front and helping us with preventive measures on imported fruit and vegetables.

Thank you, Madam Chair.

Senator COLLINS. Thank you very much, Senator Harkin, for your contribution to this Subcommittee investigation, as well as many others.

Senator HARKIN. Thank you.

Senator COLLINS. I am now, before calling forth our next panel of witnesses, going to turn to Senator Durbin to see if he has any opening comments that he would like to make.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Madam Chair, thank you for having this hearing, and I want to thank the witnesses. I am a cosponsor of Senator Mikulski's bill, as well as Senator Harkin's, and Senator Mikulski has agreed to cosponsor a piece of legislation which I bring before us, as well.

This particular issue before this Committee has a rich history. I did a little research and determined that when Senator Ribicoff was Chairman of this Committee, from Connecticut, and Senator Percy of Illinois was the ranking minority, back in 1977 they conducted hearings on this question about the adequacy of the Federal food safety inspection across America.

It was curious, and I put the chart up there just for a moment, the quote from the 1977 report of this Committee, and it said: "Divided responsibility for regulating food production has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex. We believe the bifurcated food regulation system should be unified in a single agency."

I have introduced legislation to do that, and I hope that we can in this Committee spearhead that legislation before Congress. Twenty-one years on the same song. It is time for us to basically move to action, and I commend you for your leadership in doing that.

I hope that we can come up with a bipartisan response quickly during the next session of Congress, that will not only address the questions of funding and jurisdiction, but I think the more central and unifying question about how to bring this into one agency that avoids duplication, has standards that are scientifically defensible, and basically can restore some confidence.

The testimony of Senator Harkin about the *Des Moines Register* poll I will bet would be reflected across this country. People just believe food safety is a much bigger issue than politicians do, and we have to be responsive. We should be, not only because of our obligations under our oath of office but also our obligations to our constituents.

We will now have, I am sure, an excellent panel here representing several different agencies that are concerned about this issue. I would hope that in the next year or two we could call the same group together and perhaps have one witness representing one agency with the responsibility for this—not to take anybody's job away, but to bring them together in an effort to make sure that this is more consistent.

Thank you for your leadership. You have really, I think, served the country well in raising the profile of this issue.

Senator COLLINS. Thank you very much, Senator Durbin.

I am pleased to ask our next panel of witnesses to come forward and remain standing so that I can swear you in. It includes the officials from Federal agencies responsible for regulating the safety of imported food, as well as the representative of the National Academy of Sciences.

We are pleased today to have the Hon. Raymond Kelly, who is the Commissioner of the U.S. Customs Service, the agency responsible for regulating all commerce at our borders. Thomas Billy, who is the Administrator of the Food Safety and Inspection Service of the Department of Agriculture. That is the agency responsible for regulating meat and poultry imports. William Schultz, who is the Deputy Commissioner for Policy at the Food and Drug Administration. As we know, the FDA is responsible for the regulation of over 2.7 million food shipments imported into the United States each year. And, finally, to complete our panel we have Dr. Sanford Miller, who is representing the National Academy of Sciences' Committee to Ensure Safe Food. This panel recently sent to Congress an excellent report analyzing various food safety proposals.

Pursuant to the Subcommittee's rules, all witnesses are required to be sworn, so I would ask that you raise your right hands.

Do you swear that the testimony you will give to the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. KELLY. I do.

Mr. BILLY. I do.

Mr. SCHULTZ. I do.

Dr. MILLER. I do.

Senator COLLINS. Thank you. Since we are obviously running very far behind schedule due to our late start today and the intervening votes, I am going to ask you to adhere to the request that you limit your written testimony—your oral presentation—to 10 minutes each. We will include your entire statement in the record. And the lights before you will give you guidance on how much of your time is remaining.

We are going to start with Commissioner Kelly.

TESTIMONY OF HON. RAYMOND W. KELLY,[1] COMMISSIONER, U.S. CUSTOMS SERVICE, DEPARTMENT OF THE TREASURY

Mr. KELLY. Thank you, Madam Chairwoman, Members of the Subcommittee. I am pleased to be here today to discuss Customs' efforts to address the illegal importation of tainted food, and I want to assure you that I and all of the employees of the Customs Service share the level of concern raised by the Subcommittee over the safety of food entering this country.

Those involved in schemes to knowingly violate U.S. food safety laws are driven by the same motives as those engaged in narcotics smuggling: Greed. Just as we attack illegal drug smuggling, the U.S. Customs Service will be vigilant in our efforts to keep unsafe imported food products from showing up in stores and restaurants throughout our Nation.

As you know, the U.S. Customs Service enforces more than 400 laws for 40 U.S. agencies, including the Food and Drug Administration and the U.S. Department of Agriculture. Approximately 25 percent of the enforcement work we conduct for other agencies is for FDA. We are proud of the service we provide because we know how important food safety is to the American people.

This morning in my remarks, I will address the four questions which the Subcommittee posed to me in your invitation letter of August 20. Those questions are: What are the deficiencies in the current food importing process? What specific recommendations does the Customs Service have to improve the safety of imported foods? What specific action is the Customs Service taking in response to the April 1998 GAO report on food safety? And what other changes should be considered to improve the food import process?

In response to question 1, as you are aware, through Operation Bad Apple, the Customs Service has identified a number of areas in the food importing process that could be better handled. These shortcoming can be broken down into three subgroups: Cargo control, coordination issues, and sanctions or penalties.

Cargo control deficiencies result in such scheme as banking and container switching, and also include issues related to the proper

[1] The prepared statement of Mr. Kelly appears in the Appendix on page 147.

destruction of tainted food imports. Coordination problems include the difficulty that Customs and the FDA have had in sharing relevant information on suspect imports. With regard to sanctions, the existing penalty structure may not be strong enough to effectively deter noncompliant importers.

In response to question 2, there are a number of recommendations Customs has been considering to improve the safety of imported food. We believe it is necessary to establish better control over the movement of suspect cargo through the use of technology such as discrete transponders attached to containers. We feel it is also necessary to improve current methods of targeting violative importers through expanded manipulation of existing data.

On the regulatory front, we would like to see the FDA's Notice of Refusal also serve as Customs' Notice of Redelivery. This would significantly cut down on the amount of time necessary to process noncompliant importers. And, finally, we think a national interagency team comprised of FDA representatives and Customs trade compliance experts should be established to coordinate our efforts on this front.

In response to question 3 regarding the GAO findings on food safety, the Customs Service is taking action on those recommendations which affect our responsibility. This includes better coordination with FDA, better targeting and cargo control, exploring the use of unique identifiers, destroying and/or exporting tainted food, and more appropriate assessment of sanctions against violators.

In regard to coordination with the FDA, we are reprogramming our database to extract FDA-issued refusal notices. This will allow us to have a clear list of FDA refusal actions without relying on paper copies of such notices transmitted in the mail. Again, we are seeking regulatory authority to have the FDA Notice of Refusal serve as our redelivery notice, which in so doing will automatically obligate the Customs surety bond.

With respect to targeting and cargo control, Customs is working with the FDA to target importers, high-risk producers, and FDA violative shipments nationally. We will use an automated information system to identify and subject these shipments to additional examination. We are more effectively coordinating our efforts at several ports and are experiencing increased success at those ports where interagency teams have been formed. We will look to expand this task force approach.

Although we want to better control food shipment, current resource limitations prevent us from enforcing the laws in the most effective way possible. The expanded use of bonded warehouses and centralized examination stations has been suggested. There are simply not enough examination stations at this time, and those that exist are not equipped to provide the needed storage.

As for bonded warehouses, Customs does not have the authority to require their use. Even if we did, we do not have the resources to supervise them properly. If we were to implement these suggestions, Customs would be unable to assure that switching of merchandise awaiting FDA examination would not still occur. This also is complicated by the high cost of building adequate facilities for these purposes at each port of entry.

New technologies, such as the aforementioned transponders, will help us track shipping containers from the place of unlading to the examination station. In the coming months we will test this technology at ports with high volumes of suspected food shipments.

Now, when the FDA refuses a food shipment, we work with the importer under the law to destroy or ensure exportation of that shipment. Destruction of a shipment usually occurs at a landfill or at an incineration plant. It can be difficult to determine whether a shipment presented for destruction is the actual refused entry.

Another challenge we face is that every port does not have the resources to send an inspector to witness every destruction. We estimate it would cost an additional $1.9 million annually to have inspectors witness the approximately 10,000 destructions that occur each year.

With regard to sanctions, we are seeking regulatory authority in these cases to demand more than three times the value of liquidated damages. We are also considering requiring a separate bond for each shipment for repeat violators. Customs is working with the FDA on more aggressive penalties where importers fail to export or destroy FDA-refused products.

Furthermore, as we inquire into the activities of importers, our investigative efforts often result in indictments, arrests, convictions, and fines against those making false statements, smuggling, or conspiring against the United States. We intend to pursue our investigative activities in this area and work closely with the Department of Justice to ensure those involved in illegal activities are prosecuted to the full extent of the law.

And, finally, in response to question 4, I will reiterate a point I made earlier: Our role in the issue before the Subcommittee today is not that of a lead agency, but rather as an agency brought in to assist with the enforcement of policy initiated by another agency. In this regard, I will defer to the expertise of the FDA in determining other necessary changes to improve the food import process.

In conclusion, I can assure the Subcommittee that the safety of the Nation's food supply is important to the U.S. Customs Service. We will continue to do everything we can, with existing resources and in cooperation with the FDA, to keep Americans safe from tainted and contaminated foods.

Madam Chairwoman, this completes my statement. Obviously I am available to answer any questions. Thank you.

Senator COLLINS. Thank you, Mr. Kelly.

Mr. Billy, would you please proceed with your testimony?

TESTIMONY OF THOMAS J. BILLY,[1] ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY MARK MINA, DEPUTY ADMINISTRATOR FOR FIELD OPERATIONS; AND MARGARET GLAVIN, DEPUTY ADMINISTRATOR, OFFICE OF POLICY, DEVELOPMENT AND EVALUATION

Mr. BILLY. Madam Chair and Members of the Subcommittee, I appreciate having the opportunity to appear before you today to discuss the inspection system used by USDA's Food Safety and In-

[1] The prepared statement of Mr. Billy appears in the Appendix on page 154.

spection Service for meat, poultry and egg products imported into this country. Today I am accompanied by Dr. Mark Mina, the Deputy Administrator for Field Operations, and Margaret Glavin, the Deputy Administrator of the Office of Policy, Development and Evaluation.

The FSIS inspection system ensures that all imported meat, poultry and egg products meet U.S. food safety standards as well as inspection and verification requirements. The Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act, give FSIS the authority and the responsibility to inspect meat, poultry and egg products on a continuous basis and set the food safety standards for these products.

FSIS demands and certifies that imports are produced under conditions that achieve the same level of protection as U.S.-established standards for food safety. FSIS determines the equivalence of foreign meat and poultry systems through on-site reviews involving on-site visits to the foreign countries, including randomly picking plants within those countries for inspection, and document analysis of foreign countries' laws, regulations and other pertinent information.

The amount of meat, poultry and egg products imported into the United States is very small compared to U.S.-produced products. Imported meat accounts for only about 7 percent of the domestic consumption, imported poultry totals less than 1 percent, and imported egg products also totals less than 1 percent, and these numbers have been relatively static over the last 10 years.

Not one pound of these imported products is permitted entry into the United States unless it has undergone inspection in a system certified by FSIS as equivalent to the FSIS inspection system. Only 37 countries have been certified as meeting our standards.

Meat and poultry products consumed in the United States but originating abroad are the most heavily inspected food products in the world. As I noted, imported meat and poultry are required to be inspected under a foreign inspection system that FSIS has determined to be equivalent to our own system. Then, upon arrival at the U.S. port of entry, all meat and poultry shipments undergo reinspection by FSIS. Almost all imported products, about 85 percent in total, then proceeds to a federally inspected meat or poultry plant for further processing under the supervision of FSIS inspectors.

The dramatic changes being instituted in our domestic meat and poultry inspection program directly impact foreign countries desiring to export products to the United States. In 1996, we published the pathogen reduction Hazard Analysis and Critical Control Points, or HACCP, systems' final rule.

HACCP systems are geared towards preventing problems before they occur rather than detecting problems after they occur. All of the requirements in the rule, including the microbiological testing, must be implemented by foreign inspection systems desiring to establish eligibility or to maintain their eligibility to export to the United States.

In closing, I would like to say that we at FSIS are continually striving to improve our inspection system, with a goal of minimizing the incidence of foodborne illness from the consumption of

meat, poultry and egg products, whether those products are produced in the United States or a foreign country. Thank you for the opportunity to discuss our import inspection system, and I look forward to any questions you have. Thank you.

Senator COLLINS. Thank you, Mr. Billy.

Mr. Schultz, would you please proceed?

TESTIMONY OF WILLIAM B. SCHULTZ,[1] DEPUTY COMMISSIONER FOR POLICY, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY JOSEPH LEVITT, DIRECTOR, CENTER FOR FOOD AND APPLIED NUTRITION; AND GARY DYKSTRA, DEPUTY ASSOCIATE ADMINISTRATOR, OFFICE OF REGULATORY AFFAIRS

Mr. SCHULTZ. Thank you, Madam Chairman. With me today are Joseph Levitt, who is the Director of our Food Center, and Gary Dykstra, who is the Deputy Associate Administrator for Regulatory Affairs, which is the division of the agency that oversees the field operations, including import inspections.

We appreciate the opportunity to testify, and I would like to compliment the Subcommittee on these hearings, which obviously address a very important topic, namely the adequacy of the Federal programs to assure the safety of imported food. These hearings have identified a number of serious problems. The witnesses have offered a number of very constructive suggestions.

We are not here to say that we know all the answers, but we certainly recognize that there is tremendous room for improvement in the FDA's food import program, and what I would like to do is start the discussion by talking for a few minutes about some of the trends and factors that have brought us to where we are today.

The first one is the dramatic growth of imports in recent years, and as you can see from the chart, in the mid-1980's there were about 1,000 what we call line items of food offered for import in the United States—not 1,000 but just under 1 million line items offered. If we jump to 1998, it is over 3 million. And what that means is, today a significant amount of the food that we eat in this country is imported. That includes over 50 percent of seafood that is consumed, 38 percent of fresh fruit, and about 12 percent of fresh vegetables.

Second, the imported food that we are seeing is much more complex than it used to be. In the past, many imports were raw materials, bulk products, products that were brought into the United States and then used in processing food, so the food was both inspected at the border but then often it could be inspected domestically when the FDA inspectors went into processed food facilities. Today what we are seeing is fresh produce, fresh seafood, and thus it is all the more important that we get it right before the food comes into this country.

Making the problem even more difficult is, as has been mentioned in testimony, what we call emerging pathogens. We are seeing, both domestically but also in imports, kinds of bacteria that we just didn't see only a few years ago. They are often hard to detect,

[1] The prepared statement of Mr. Schultz appears in the Appendix on page 159.

and they are often more virulent than what we have seen in the past.

And then finally is the issue of resources, which simply are not sufficient to do the job. So the bottom line is that while food imports have increased by more than 300 percent in recent years, the FDA's resources devoted to this program have not only failed to keep up, they have been declining slightly.

That is the bad news. Now I would like to give you the good news. The good news is that food safety today is front and center at FDA. In recent years our agency has had what I think are some great successes. We have fixed the drug lag. We have greatly improved medical device review times. And then just recently we have put a tremendous and, I think, very successful effort into implementing the FDA Modernization Act, which this Congress passed just a year ago.

But during those years food safety has been, frankly, on the back burner. That is no longer true. For the last 2 years food safety, which includes of course the safety of imported food, has been a priority.

Part of the answer, we think, is new resources, but that is not the whole answer. Instead, there is also tremendous room for improvement in our existing program, and in this regard the General Accounting Office report that you commissioned makes a number of very important suggestions. And those suggestions range from how FDA sets its priorities to authorities that are needed, including for example one simple authority, which would be the ability for FDA to require that goods that are refused import be marked so that they can't be reimported from another port.

But in addition to the resources and improving the existing program, we believe that a whole new approach is needed to this problem, and that we can no longer simply rely on inspections at the border. Instead, we must find a way to prevent food from being contaminated before it is brought to our border. We must find a way, in other words, to go the source of the potential contamination.

And thus it is our view that the import program of the future will look very different from the import program that you are examining today. While we will continue to rely to some extent on dockside inspection, we know that even with a vast increase of resources, those kinds of inspections won't be adequate.

And therefore, any new resources that FDA gets, a considerable amount of them would be devoted to working with foreign governments in improving their regulatory systems, and to basically going abroad, looking at the farms, looking at how the food is produced, and strengthening those systems. The goal of this would be that any food imported into this country be produced in a country that has a regulatory system that is as good as the one in the United States.

As part of this program, we believe that FDA needs the ability to refuse imports from a country that doesn't have an adequate food safety regulatory system of its own. Implementing this kind of program will take time, but we believe that for the future it is essential in order to assure the safety of imported food.

In conclusion, Madam Chairman and Senator Durbin, I would like to say we appreciate the support of the Members of this Subcommittee in voting to increase our food safety budget when the appropriations bill was amended on the Senate floor last July, and in the coming months we look forward to working with you on substantive legislation and on other measures that we can take to improve this program.

We would, of course, be happy to answer any questions.

Senator COLLINS. Thank you very much, Mr. Schultz.

Dr. Miller, we look forward to your testimony.

TESTIMONY OF SANFORD A. MILLER,[1] MEMBER, COMMITTEE TO ENSURE SAFE FOOD FROM PRODUCTION TO CONSUMPTION, NATIONAL ACADEMY OF SCIENCES

Dr. MILLER. Thank you, Madam Chair. I am Dr. Sanford Miller. I am Dean of the Graduate School for Biomedical Sciences at the University of Texas Health Science Center in San Antonio, and I served as a member of the Committee to Ensure Safe Food From Production to Consumption of the National Academy of Sciences. It is in that context that I join with you today.

I am pleased to have this opportunity today to comment on this issue of food safety, so vital to the public health. The study that I will address today was requested by Congress. In order to provide a context for the issues related to imported foods contained in our report, I would like to first address the questions you asked related to the recommendations included in the report, and then follow by addressing the findings of the committee related to imported foods in response to the other two questions that were posed by the Subcommittee.

The first question was, What recommendations were offered by the committee to establish an effective food safety system? The report, "Ensuring Safe Food From Production to Consumption," came to three primary conclusions, and from them, several recommendations.

The first conclusion was, "An effective and efficient food safety system must be based in science." The second conclusion which follows from that was, "To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised."

This second conclusion resulted in two recommendations: First, that Congress should change Federal statutes so that inspection, enforcement and research efforts can be based on scientifically supportable assessments of risks to public health. Some of the science-based changes in Federal statute proposed by the committee were elimination of the current continuous inspection system for meat and poultry and replacement with a science-based approach which is capable of detecting hazards of concern. Second, mandating a single set of science-based inspection regulations for all foods; there are common factors for all foods. And, third, requiring that all imported foods come only from countries with food safety standards deemed equivalent to U.S. standards.

[1] The prepared statement of Dr. Miller appears in the Appendix on page 180.

Second, the second conclusion, that Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs, including research and education programs, should be allocated in accordance with science-based assessments of risks and possible benefits to the public.

A well-developed national food safety plan formulated by Federal food safety agencies, and with representation from the many stakeholders involved in ensuring safe food, is vitally needed. It should include consideration of the distinctive efforts required to ensure the safety of imported foods, and a plan to address consumers' behaviors related to safe food handling processes, since that is the final line of defense.

The third conclusion was related to the need for reorganization of food safety efforts in the United States: "To implement a science-based system, reorganization of Federal food safety efforts is required."

This resulted in two recommendations: First, to implement the science-based system, Congress should establish by statute a unified and central framework for managing Federal food safety programs, one that is headed by a single official, and which has the responsibility and control of resources for all Federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The current fragmented regulatory structure is not well-equipped to meet current challenges. In order for the organizational structure not to be a barrier to food safety, one official should be responsible for Federal efforts in food safety and have control of all resources allocated to food safety. An identifiable, high-ranking, presidentially appointed head whose appointment is based in statute, and thus is not temporary or easily changed by political agendas or executive directive, is required to direct and coordinate Federal activities and speak to the Nation, giving Federal food safety efforts a single voice.

Since the Food Safety Council recently established by the President's executive order was announced following release of the committee's report, our report does not identify or evaluate that organizational structure.

The second recommendation regarding organization structure is as follows: Congress should provide the agency responsible for food safety at the Federal level with the tools necessary to integrate and unify the efforts of authorities at the State and local levels to enhance food safety. This would include statutory measures and funding necessary for the Federal Government to be able to ensure nationwide adherence to minimal standards when it is deemed appropriate.

Now, if I may, I would like to address the questions of imports and risk assessment. With regard to how scientifically supportable assessments of risk to public health can be used to create more effective safeguards to protect the public, and the extent to which resources can be better allocated if regulatory decisions are based on scientifically developed data, the report does point out that decisions need to be based on assessments of risk to public health, and

that resources should be allocated towards those that indicate the greatest risk to health.

However, the report also recognizes that great gaps exist in the information needed to develop some of these assessments, in which case judgments need to be based on whatever scientific data happens to be available. Therefore, significant research is required to fill these gaps. Some hazards may need to be provided resources even though there may be other areas that pose greater risk to public health, but for which additional resource allocation would have little likelihood of more effectively protecting the public health at this time.

With regard to the current import process and possible deficiencies, if any, identified by the NAS report, the committee recognized that the globalization of the U.S. food systems brings foods from all parts of the world into the U.S. marketplace, and with it the potential for foodborne infections or other hazards not normally found in the United States. In the United States, the production, processing and shipment of food can, in theory, be subject to government monitoring from harvest to consumer purchase, but imported food is not subject to similar oversight.

It is by no means clear that imported food as a class poses greater risks than does domestically produced food. What is clear is that Federal officials cannot use the same methods to regulate imported food that they use, or that would make sense, in regulating domestically produced food. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance and inspection activities within other countries in accordance with science-based assessments of risk and benefit.

The laws that FSIS and FDA administer require that imported food meet the same standards as domestic food, but, as the Subcommittee is well aware, the enforcement approaches of these two agencies to meet this common requirement are quite different. The different systems of scrutiny of imports used by FDA and USDA largely mirror their different approaches to domestically-produced food, as is required, since they must document domestic equivalence.

USDA statutory authority requires meat and poultry food safety systems of exporting countries to be equivalent to the U.S. system. However, FDA lacks the authority to require that imported foods be produced under a system equivalent to the one that it administers domestically. Instead, FDA, as you know, relies primarily on sampling at ports of entry to determine whether food imports meet domestic requirements.

Even if FDA's criteria for sampling and testing were systematically risk-based and its resources were adequate to keep up with an increasing volume due to increased demand, sample analysis alone is not capable of detecting many of the most serious risks to consumer health. There is currently no way to determine whether the agencies are focusing their attention on the most important health risks.

In an effort to address the challenges of ensuring the safety of imported foods, the President has proposed a variety of measures, including hiring additional FDA inspectors to examine the safety of

fruit and vegetables in the marketplace, both domestic and imported. Recognizing that sample analysis alone does not provide a means for detecting many of the most serious risks to consumers' health, and without firm knowledge of the most significant risks, it is simply impossible to know whether these proposed actions will adequately address imported food hazards.

On behalf of the National Academy of Sciences' Committee to Ensure Safe Food From Production to Consumption, I thank you, Madam Chairman and Senator Durbin, for this opportunity to present our testimony at this hearing, and of course we will be happy to respond to any questions.

Senator COLLINS. Thank you very much, Dr. Miller.

We will now have a 10-minute round of questions per Senator, and I would like to start with you, Mr. Schultz, to talk about the issue of equivalency authority. You and I have talked privately, and as well as in your testimony this morning, you have made the point that with the huge volume of shipments that the FDA has to deal with, which your chart well illustrates, when you're dealing with 2.7 million shipments per year, that even if we quadrupled the number of inspections, that you can never catch up. Is that fair? And given the fact that many emerging pathogens are so difficult to detect from a visual inspection or even sampling, that we are still not getting at the root of the problem?

Mr. SCHULTZ. That is right. Today we only look at 1.7 percent of imports, so quadrupling it we think still would not be the answer.

Senator COLLINS. And that is the appeal of having some sort of equivalency standard; of saying that unless other countries meet American standards, we are not going to import fruit and vegetables from them, similar to what FSIS does, but there are some important differences.

And that approach has a great deal of appeal to me because it does go to the root cause, but I am concerned about how practical it is. And I think there are a lot of issues that we need to work through before going that route, even if that is the ultimate answer.

In 1994, GAO, which has been advocating equivalency for some time, issued a report calling for equivalency, and FDA said then that it would "be virtually impossible to impose U.S.-equivalent regulations on other nations," and FDA drew the contrast that fruit and vegetables are produced in decentralized locations, as opposed to FSIS is mainly dealing with centralized processing plants or slaughterhouses when it comes to meat and poultry.

Given those differences, how would you go about implementing equivalency? How practical is it?

Mr. SCHULTZ. It is a very important point, Senator Collins. As I understand it, equivalency has special meaning in the international trade jargon. It involves what is a certification of the other country's system, and it often involves an agreement that takes a lot of resources and a long time to negotiate. We don't know that full equivalency, mandatory equivalency, is necessarily the best approach.

What we do think we need, though, is both the resources to go and work with other countries to strengthen their systems, and the

authority to be able to say to those countries, "If your system isn't adequate, if it's not as strong as ours, then we have the ability to refuse to import your product.

We want to put the responsibility back on you, not that you have to do it exactly the same way the United States does, but that basic sanitation measures and so on must be taken."

And we need a way not just to work with them but to make them listen to us when we tell them: "You need to strengthen your system. Otherwise, we may choose not to import your food."

Senator COLLINS. Some domestic fruit and vegetable producers have raised concern to me that if we move to an equivalency system, that it will mean that FDA or the Department of Agriculture has to impose a whole new set of burdensome regulations for our domestic industry, when there isn't necessarily a problem, in order to show equivalency or equivalent standards. Could you comment on that issue? Is that fear justified?

Mr. SCHULTZ. I think it is an understandable concern but I think it is a misunderstanding of the approach that we are advocating. It is true that in order to tell another country or talk to another country about what its standards ought to be, you have to know what your own standards are. But those standards are found in our laws, in our regulations, and we are also issuing guidances to our own industry about what the standards are.

Here we are talking mostly about basic sanitation standards. We are talking about standards that already exist in this country, and what we need to do is describe them so that other countries know what we are expecting of them.

Senator COLLINS. So if we move to that system, you would not see it as imposing a host of new regulations on domestic producers, because we are in essence talking about basic sanitation standards which they already meet. Is that accurate?

Mr. SCHULTZ. We think that is accurate. We think we have a very important education role to play, and we have started on that. We believe we are having success in talking to our own agricultural industry and in explaining what we have in mind.

There are, of course, variations in this country, and I don't want to sit here and say that every facility in this country is going to meet those basic standards, but we are talking about basic standards that we believe most of the facilities do already meet.

Senator COLLINS. Could you explain to the Subcommittee what authority the FDA currently has to ban a product that is suspected of containing pathogens? In the case of the Guatemalan raspberries, which this Subcommittee explored in depth, the FDA did take action to ban the importation during the spring months when the problem with *Cyclospora* contamination was greatest, so you obviously have some existing authority to protect the public health.

Mr. SCHULTZ. Right.

Senator COLLINS. What is that authority? Do you need new authority that goes beyond that?

Mr. SCHULTZ. We are now looking at this, too, I must say, and there are debates about it. But the basic approach we have taken up to now is reactive. In other words, we identify a problem such as Guatemalan raspberries, we look at the product and we know there is a problem with the product, and then we have the author-

ity to take action which can go as far as banning the product, but it is where we know there is a problem.

What we are looking for, toward, in the future is a preventative approach where we can say we might not know about this particular product, but we can see from the way products are handled in your country, from the lack of regulation, that there is a potential for a problem, and we basically want to work with you to improve the system in your own country. But you need to know that if you don't do that, we have the ability to prevent the import, not because we are looking at the product but because we can see the potential for a Guatemalan raspberry type of situation in the future.

Senator COLLINS. Mr. Billy, I want to explore with you how the equivalency process works for FSIS. Now, in your case it is my understanding that you have equivalency agreements or certifications with 37 nations. Is that correct?

Mr. BILLY. Yes.

Senator COLLINS. We know that our Nation is importing fruit and vegetables from considerably more countries, some 90 nations. Have you turned down specific countries, or are you still going through the process of certifying their standards? Give us some idea of how the 37 countries compares with the 90 countries that are now exporting fruit and vegetables to us.

Mr. BILLY. We currently have 20 countries in the queue, lined up to demonstrate that they have equivalent inspection systems, standards, laws, regulations, to qualify for exporting meat and poultry products to the United States. And we are very actively involved in reviewing first the paperwork and the actual systems in place, and if we ultimately conclude that they are equivalent, then we will certify them and permit the shipment of products to the United States.

We have in the past declined to approve countries. We have also delisted countries when we found that their systems changed and became unacceptable in terms of—or not qualifying in terms of equivalency.

I think this idea of equivalency is at the heart of the success that we have in terms of dealing with imported meat and poultry products. As I assume you are aware, I worked for the Food and Drug Administration, and I was frustrated by the limitations that they had in terms of their authorities, and I think this is a very important area that this Subcommittee needs to look at and judge.

Finally, we just recently put in place our new HACCP regulations, and we are now in the process of going back through all of the 37 countries to verify that in fact the new regulatory requirements have been addressed by these 37 countries, and ensuring that they have in place HACCP-type regulations that have been implemented, that the slaughter plants are testing their processes for *E. coli*, and that they are going to meet the salmonella performance standards that were established. So this is not a one-time effort. In other words, it is an ongoing effort, and you need the resources, the capacity to deal with it on an continuing basis.

Senator COLLINS. Have the international trade agreements posed any difficulties for you in negotiating or certifying the equivalency standards in other countries?

Mr. BILLY. I can say this, that at this time we haven't been challenged in terms of our approach to determining the equivalency of the foreign systems. That concept in the new requirements in the trade agreements is relatively new, and we are working hard to ensure that the approach we take will work not only effectively for us in terms of imports, but also with regard to what we would expect when we export food products. We are one of the largest exporters of food worldwide, and this same concept I believe will work well for us in terms of sustaining and hopefully increasing our exports worldwide.

Senator COLLINS. Thank you. My time has expired.

Senator Durbin.

Senator DURBIN. Thanks, Madam Chair.

Let me ask just one threshold question which I think I know the answer to, and that goes back to this finding not only by the National Academy of Sciences but the General Accounting Office on 12 different occasions over the last 6 years calling for one single Federal food safety and inspection agency with coordinated jurisdiction, scientifically-based.

Is there any member of the panel, particularly Mr. Schultz or Mr. Billy, who disagrees with that? Do you think that that standard will not result in a safer food supply, saving taxpayers some money, and at least making the bureaucracy more comprehensible to those who are affected by it?

Mr. SCHULTZ. Senator Durbin, as you may know, after the NAS issued its report, the President established a council, and one of its charges was in 180 days to look at this very issue and make a recommendation. So the report is being studied.

The administration did 2 years ago issue a report, and I would like to submit it for the record.[1] It is called "Food Safety From Farm to Table," but it is a comprehensive approach to food safety that includes risk assessment, research, and inspection. Coordination is a big piece of it, and surveillance by the CDC. And I would like to submit it and ask anybody who is interested to look at it. This here to date has been our approach to the issue.

Senator DURBIN. Mr. Billy.

Mr. BILLY. I agree that I think it is important for the new Food Safety Council established by the President to do a comprehensive review of all of the recommendations made by the National Academy. I also would point out that the new council plans to establish a National Strategic Plan for Food Safety, and that is one of the key recommendations made by the Academy. The new council plans to develop a unified food safety budget and submit that annually to the Congress. That is another recommendation of the National Academy.

And, as Mr. Schultz has indicated, we plan to do an in-depth review of the Academy report, so I think we ought to provide an opportunity for that to occur and then see the specific conclusions and reaction of the administration to that Academy study.

Senator DURBIN. This is a serious issue. We should take it seriously. We should make certain that the procedure that we follow

[1] The report appears as Exhibit No. 5 in the Appendix on page 386.

is one that is in the best interests of food safety, among our major obligations to people in this country.

Having said that, 21 years ago this Subcommittee accepted the premise that we have too many Federal agencies that have responsibility in this area. Twenty-one years ago they started calling for us to consolidate this, maybe even before, but at least 21 years ago, into one agency.

I have introduced legislation with Congressman Fazio and Senator Torricelli in an effort to do that. Why don't we just accept the premise that we should have one agency, scientifically based—and then talk about how we reach that goal? I hope—I don't want to sound frustrated, but I am—that we can at least agree on that.

Dr. Miller, I see you shaking your head. I think after your study you understand that.

I want to ask some questions of Mr. Kelly, and I thank you for being here today. Senator Collins, when she called the last hearing, brought before us testimony from people who are involved in this business of food importing and how they defraud our process and our government, and you have done some good work with the Customs Service. Let me talk about two specific areas and ask you what you would do about them, and you mentioned them in your testimony.

You testified that "banking and switching" by importers poses a continuing challenge. Are there specific solutions for tagging food in some way that will help prevent or eliminate this problem?

Mr. KELLY. We are looking at a variety of things, Senator. We think technology in this area can certainly be helpful. We are looking at ways to perhaps use identifiers that only come out under black light, putting markers on containers. We are exploring a whole array of areas, but right now, it is unrealistic to think that we have the resources to adequately trace a load of suspected food from where it is stored to, let's say, an incineration plan. I believe technology is the answer in this area, and our people are looking at a variety of things. I think we will come up with something in the near term.

Senator DURBIN. Do you have the resources to do this? I mean, is it within the Customs Service resources, budget, and ability to try to find this new technology?

Mr. KELLY. Yes. I think we can find the technology. The money to purchase the technology might be another issue.

Senator DURBIN. Another story, but once we come to that conclusion, do you feel you can reach some sort of a finding that will lead us to that?

Mr. KELLY. Yes, sir. Now, we have a lot of talented people in the technology area that have some pretty innovative ideas. I believe the agency can come up with the solution. Finding the resources, of course, is always a challenge.

Senator DURBIN. Let me ask you another question: Do you think that the current policy of giving importers the option of destroying the rejected shipment or reexporting the product back to its origin or elsewhere is a problem?

If you had been here at the previous hearing and heard the testimony—this will put you off your feed for a few minutes—of a shipment of fish, if I remember correctly, rejected, then returning to

the United States several years later as frozen fish, here it comes again. Why shouldn't destruction be the only recourse, given some of the reported incidents such as this that find these rejected, unsafe, adulterated products finding their way back to the United States even years later?

Mr. KELLY. Senator, it makes sense to me to have destruction be the only alternative. However, I am pretty new at my job, about a month and a half, and I think we have to think out all of the consequences, or at least I have to have them explained to me. But certainly my initial reaction is, why reexport?

Senator DURBIN. Does Customs have the authority to bar violators, such as the top ten identified in Operation Bad Apple, from importing or doing business?

Mr. KELLY. No, sir, we do not have that authority.

Senator DURBIN. What factors do you take into consideration in determining fines and penalties?

Mr. KELLY. The record of the importer obviously is a significant consideration. If in fact one is a repeat violator, then the fines themselves would naturally be increased.

Now, we are limited as far as imposing fines, moving against the bond, to three times the entry value. So even if we find an egregious violator and we are moving in that area, we are limited to three times the entry value. We are examining the possibility of expanding that to a level of the domestic value, in other words the market value of what the commodities would bring.

There is a whole series of areas that we look at, particularly the record of the individual, the size of the shipment, those sorts of considerations, in determining a penalty.

Senator DURBIN. And do I understand that you are considering raising the bond requirements for repeat offenders?

Mr. KELLY. We are considering raising the bond requirement, yes, sir.

Senator DURBIN. Well, let me say that the testimony we had from a previous hearing suggested that some of these folks consider this the cost of doing business. They will just violate the law and hope they don't get caught, and assume that when they do, it is just another cost. It really doesn't slow them down or stop them.

When I hear that you don't have the authority to literally ban them from future importation in the United States, and that you are really limited in the fines you can charge, I am glad to hear that you are taking another look at it. I think that is critically important.

Mr. Schultz, let me ask you the same question about reexport or destruction. I think that is something that the FDA should be thinking about, as well.

Mr. SCHULTZ. I agree that it is something we should look at carefully. I am reluctant to give you a categorical answer because I can imagine a situation where the violation is pretty trivial, not necessarily going to the safety of the food. It could go to the labeling or something, where the food could be rehabilitated, and you are obviously talking about very large amounts of money on occasion. So I am a little reluctant to give you a categorical answer, but I think I agree with your sentiment.

Senator DURBIN. People make mistakes, but the testimony before this Subcommittee—was it rice sticks that we were dealing with here? We had a company that clearly was a bad actor, and decided to mislabel their product in order to escape inspection and scrutiny. And so I think we ought to have some sort of a fair judgment standard here, that if it is an innocent mistake, it is one thing, but mislabeling in and of itself can be reasons for us to come down hard on these people.

I see my time is about to expire, Madam Chair. I see Senator Levin is here, but I will try to stay for another round of questions. Thank you.

Senator COLLINS. Senator Levin.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Thank you, Madam Chairman, and thank you again for your leadership in this area. It is critically important, and it has been very, very strong, and we are all in your debt and the Nation is in your debt for doing what you are doing here.

I am interested in the weak fines to start with. We have got maximum fines, as I understand it, FDA, for the misdemeanor, of $1,000 or a year in prison. I doubt very much that the prison sentence is used very often, although I could ask you about that, but a $1,000 fine, it seems to me, for introducing bad food into this system of ours, is just nothing. It is hollow. There is no threat there; there is no deterrent.

I am wondering if you would comment on this, Mr. Schultz, because I am very much interested in introducing a bill, and I will be, that would significantly up the fines for violations of our laws, both misdemeanor and felonies, both for FDA and for the Department of Agriculture. But first, your comment on the current system. Is it as weak as it seems to me in terms of penalties and fines for violations?

Mr. SCHULTZ. We agree that there are serious inadequacies, and we would be happy to work with you on legislation. While the criminal sanctions are important, I think it has been pointed out they often don't work. They can be too harsh. They require the Justice Department agreeing to bring a prosecution, and the Justice Department has to weigh this against everything else it is doing. And we do have to find a way so that importers don't regard the fines or the forfeiting of bond as simply the cost of doing business.

Senator LEVIN. Well, there is a number of ways in which we can deter. And we have talked about equivalency is one way of doing this, as well, and I want to get to that, as others already have, in a moment.

But if people face significant penalties for violation, at least it is something of a deterrent. If they face a $1,000 fine, or if they just simply lose their bond and their bond is three times declared value, and declared value is much less than what the value is on the domestic market, it becomes a hollow threat. And so these penalties do provide some deterrent, and that is why I want to focus on this.

One additional way to apply a penalty is a civil penalty, so that you don't rely so heavily on the Justice Department. And, again, I am going to be addressing this in legislation. Have you looked at that possibility, at other agencies', indeed your own agency's use of

civil penalties? Why should we not here provide for the possibility of a civil or an administratively laid penalty, as well as the possibility of a criminal penalty?

Mr. SCHULTZ. And GAO recommended this, and we think it is a very constructive recommendation. We would be happy to work with you.

Senator LEVIN. And, Mr. Billy, let me ask you the same question for the Department of Agriculture. Your penalties are about the same, $1,000 for a misdemeanor. I believe you have a slightly larger one for a felony, but—and the jail term, it seems to me, is not a realistic, likely outcome as a practical matter in the world in which we are in, in terms of all the priorities we have. It just isn't likely to happen. Whether it should or not is a different issue. But we have to hit folks in their pocketbook, and it seems to me we are not doing that in many ways. So, Mr. Billy, would you comment on the fine formula that you folks use at Agriculture?

Mr. BILLY. We have an inadequate inability to assess civil fines to enforce our regulations. We sent forward legislation which was introduced by Senator Harkin. It is called the Food Safety Enforcement Enhancement Act. It was introduced last year, and it lays out specifically the kind of civil penalty authority we would like to have, and we think this is a critically important tool we need as we move forward in terms of improving food safety.

Senator LEVIN. And in addition to civil penalties, your penalty for—your criminal penalty is $1,000, is that not correct, or a year in jail, for a misdemeanor?

Mr. BILLY. Yes, but we do in fact use the criminal penalties provisions, and there are several people currently in prison that are there because of serious violations of our regulations.

Senator LEVIN. Is that for a misdemeanor violation or a felony?

Mr. BILLY. Felony violations.

Senator LEVIN. On the misdemeanor side, do you have any folks that have been given a year?

Mr. BILLY. No. We need additional authority there to deal with that area, as well.

Senator LEVIN. All right. And is it not correct that your fine on the misdemeanor side is $1,000?

Mr. BILLY. I believe that is correct, but I would like to check that.

Senator LEVIN. All right, and you could use some additional strength there?

Mr. BILLY. We could definitely use some additional strength there.

Senator LEVIN. All right. The bonding issue which Customs has talked about, I think has already been addressed in Senator Durbin's questions. Perhaps other Senators have also asked questions about it, so I will not ask about that, but I think that is also a very helpful direction.

On the equivalency issue, one of the arguments which the Chairman said has been raised against equivalency is the issue of whether or not that would then lead to greater domestic regulation, and your answer I believe was that in your judgment it would not.

Is there any reason why a bill that would be granting FDA equivalency authority should not contain a provision which says

"nothing in this bill is intended to require the FDA to do any regulation that it otherwise would not be doing anyway"? That is not a very artful or legal way to phrase it but I think you get the drift——

Mr. SCHULTZ. Right.

Senator LEVIN [continuing]. That the bill isn't intended to force you to do regulating you wouldn't otherwise do, just to say in the area where you have regulated and you have standards, that we simply want other countries to have equivalent standards if they are going to import foods into the United States.

Is there any reason that you can see why such a bill could not contain that kind of language?

Mr. SCHULTZ. No. Obviously we want to look at the language. I would want to consult with the lawyers and others at FDA. But sitting here, I don't see a reason why that would be a problem.

Senator LEVIN. Well, it is something perhaps that could be considered as a way of addressing the issue which has been raised, which the Chairman has already referred to.

Just one other question that I have, and that relates to the equivalency as well, and that is another question which the Chairman has raised. She said that one of the questions is whether or not we would have the resources to go into other countries and inspect, and because it is so decentralized in other countries compared to slaughterhouses, that it would be a much more difficult inspection system.

But even if there were very modest inspection in other countries, isn't equivalency at its heart a determination by the agencies that the other countries have a system which will give us the same level of protection? And even though our inspection to assure that that is true may be less than desirable, nonetheless, it doesn't take a whole lot of inspection to see whether there is a system in place. Now, whether it stays in place and is applied to every decentralized field or producing facility is a different issue. But isn't the heart of equivalency that determination as to whether a system is in place, and that indeed does not require a huge amount of inspections or resources?

Maybe Mr. Billy first, because I think they have got a system.

Mr. BILLY. I think you have put your finger on something important here, and it does take some resources, and I will use an example, but I think your point is well taken. It is the system that you are looking at and evaluating, and a lot of that can be done through the exchange of material, periodic visits by inspection personnel and others that validate or verify that the system will be reliable.

But I also want to point out that, as I mentioned earlier, we now are verifying that the 37 countries are complying with our new regulatory requirements or HACCP, and it is no small task. We have received volumes of paperwork from these countries in their home language, which we have translated to provide the basis for us to make these evaluations. So there is an infrastructure that is needed with the capacity to deal with even this kind of systems evaluation. But I think your point is well taken in terms of the system being the point of emphasis.

Senator LEVIN. Thank you. Thank all of the witnesses, and Dr. Miller particularly, thanks to the Academy for the important work you have done in this area.

Dr. MILLER. Thank you.

Senator COLLINS. Thank you, Senator Levin.

Our witnesses may feel that they have caught a break. We have another vote that has just begun. We have time for one more round of 5 minutes each per Senator, and then I am going to ask that we submit the rest of our questions for the record, and I will adjourn the hearing when we go to vote. We look forward, however, to continuing our dialogue with all of the witnesses.

Commissioner Kelly, I want to ask you a little bit more about the idea of using a bonded warehouse for some shipments to be held if they are suspected of contamination. Some of the weaknesses that we have uncovered in the process is that FDA, unlike FSIS, allows the importer to keep control for up to 90 days of the suspect shipment, and also allows the importer to select his or her own laboratory to perform the tests. There is lots of opportunity for deception and fraud in the process.

You mentioned, and I think it is a very valid point, that given the huge number of shipments we are talking about with the FDA, that requiring the use of bonded warehouses is probably not practical. It would be too costly. However, isn't there another approach?

I know we talked at the last hearing that Customs had a top 10 list of violators of our import laws. I personally think anyone who makes the top 10 list should probably be banned from the industry forever. But couldn't we have a middle ground where problem importers who violate health and safety laws are required to have their goods controlled at a bonded warehouse? Do you think that would be an appropriate approach?

Mr. KELLY. It might very well be, Madam Chairwoman. However, I am told that we don't have the authority to do that now, and then there is an issue of supervision. Once you put something in a bonded warehouse, Customs or some entity has to supervise it. We have problems with other bonded shipments now. I mean, I think the whole area has to be looked at in depth. That is something we intend to do in the Customs Service.

But it is complex, and we just—again, it is an issue of space. If we could identify the top 10 violators, then it may in fact have some viability and be something we should look at. But, again, we are all under resource constraints, and when you talk about supervising even the top 10 violators, you know, it is a drain. But it is something I would be glad to look at and get back with a more specific answer to you.

Senator COLLINS. I would appreciate that, and if you have specific suggestions for statutory authority in any of these areas, and I would say that to all three of the agencies represented here, we really do want to work with you to give you the tools that you need.

Another follow-up with you, Commissioner Kelly, on an issue that was raised at our previous hearing. At our September 10 hearing there were a lot of coordination problems between Customs and FDA that were discussed. For example, in the Port of New York we found that the Customs Service was unaware of 63 FDA refusal notices.

Now, it would help, and I think this is something that ought to be implemented, if FDA stamped the product "refused U.S. entry" much the way FSIS does. At least then the importer has to go to the trouble of repackaging it. I mean, at least we are making it a little bit harder.

But it is troubling to me that there was that lack of coordination, and in 48 of those 63 cases we are pretty certain that the unsafe food actually entered into the American marketplace. I know that in your written testimony you suggested a possible solution to this problem, but I would like to get that on the record.

Mr. KELLY. Yes, I think we need a lot more coordination with the FDA. As a matter of fact, we have a meeting I believe scheduled today. There is a lot of good things happening. There is a joint task force, if you will, in Miami, where FDA and Customs officers are working together. I think we will look to replicate that where it is appropriate in other areas of the country.

We are talking about a more effective interface between our data systems, FDA's and the Customs' systems, that should address the issue that you raised, and I am told that that will hopefully be ready to go forward at the beginning of the calendar year.

Senator COLLINS. And you are thinking of using FDA's refusal as a redelivery notice for Customs?

Mr. KELLY. Correct.

Senator COLLINS. Is that a part of it, as well?

Mr. KELLY. That would cut down the time to implement the penalty process, if you will. But it really is a duplicative process now, and that is what we are looking to do, to use their refusal notice as the notice for redelivery. Precisely.

Senator COLLINS. It seems like a good, practical suggestion.

Dr. Miller, I just want to ask you one question before I yield to my colleague, Senator Durbin. About the time that your report came out, the President announced that he was forming this coordinating committee. I realize that doesn't go as far as what the National Academy's study has recommended, which is similar to the approach that Senator Durbin is advocating. But do you see this as a good first step, or what was the reaction of your organization to the coordinating committee approach?

Dr. MILLER. Well, since the committee had ceased its work at the time when the announcement was made, the committee had never—had not had the opportunity of evaluating it. So I can't speak for the committee nor can I speak for the Academy, but if you want a personal view——

Senator COLLINS. I would.

Dr. MILLER [continuing]. The answer is yes. I think it is a good—it is a first step, a small one, but a first step, and at least it recognizes the realities of the current situation concerning the interaction between the agencies.

Senator COLLINS. It strikes me that one possible option for this Subcommittee to consider is codifying the coordinating committee as sort of a middle ground between those who would like a single food agency and those who are adamantly opposed to any change in the current process. That is something that I want to explore with Senator Durbin at some point.

I am going to yield to Senator Durbin. I asked the staff to call to make sure that the vote is held for both of us. Senator Durbin.

Senator DURBIN. Dr. Miller, would you address this issue of equivalency we have talked about here?

Dr. MILLER. Yes.

Senator DURBIN. I mean, the thing that comes to my mind is, a lot of the contamination that we are talking about in imported fruit and vegetables has a lot to do with sanitation facilities in the fields. And if we were to say we are going to demand a certain level standard, let's just address that one aspect of the problem, would we be able to say that if you just lived up to the standards that we impose on growers in the United States, that that would meet the safe level in terms of health and the like?

Dr. MILLER. Yes, that is a very interesting question. The committee, in discussing this issue of equivalency, in our discussions, and it didn't show up in the report per se, but we all understood that when you talk about equivalent you don't mean identical. It means that the outcome is the same.

And different countries have different problems. For example, in terms of water, in some countries of the world you can rest assured that what you are not going to have is, in fact, clean water. In the United States, on the whole, you can be pretty well assured you can.

So you have to set up different ways of approaching it. The only way to assure yourself of this is that what comes out the other end is the same, and that you have identified where the problems are and you do something to deal with it, and sanitation is the basic thing.

Senator DURBIN. What I am asking about is the threshold that we have established in the United States for sanitation, just to take that, when it comes to workers in the fields harvesting fruit and vegetables. If we were to say, "All right, if the rest of the world lives up to this standard," then at least that concern wouldn't be on the table?

Dr. MILLER. Oh, right. We certainly can't ask other countries to do better than we do ourselves.

Senator DURBIN. No, but let's say if we asked them—what I am getting at——

Dr. MILLER. We have got standards.

Senator DURBIN [continuing]. Do we have a standard that is good enough now for the National Academy of Sciences to say, "If the rest of the world followed this," that would at least allay some of our fears?

Dr. MILLER. As a general rule, yes. I mean, there are always exceptions. One thing the scientific community can always do is find things wrong with things, and there are things that could be made better, and there is no question about it. But I think, on the whole, I think you have to say that the food supply that is supplied to the American people is pretty safe, and that is because the standards we use are enforceable standards and the products that we turn out are safe.

Senator DURBIN. Well, I am glad you said that, because it goes back to the Chair's question, concerns expressed to her about if we are going to call for equivalency, does that mean higher standards

for the United States? And I think your answer is that if other countries could come close to meeting our standards, that it would solve some of the problems here.

Dr. MILLER. I can only make, if I may, just one further recommendation to the Subcommittee, if I can. We have concentrated and we seem to be focused entirely on the issue of pathogens in food, and correctly so. That is the most recent problem, and it is one which in part has come about because we focused for so many years on the chemical components of food, chemical contamination, and food additives.

Since I have been talking about this for many years, as my colleagues know, arguing that we haven't paid enough attention to pathogens, I find myself in the unenviable position of having to say, "Now, wait a minute, let's not forget about the other part of it, too. In our efforts to deal with pathogens, let's not do what we did to them in the first place, and stop doing the things that assure us safe food in terms of chemistry."

So I would simply suggest that in any legislation you consider, you think about food safety in its broadest context, not just in terms of pathogens.

Senator DURBIN. Thank you, Dr. Miller. I have another line of questions but we won't have time for it, because I would like to walk through with the FDA exactly what is happening at those ports of entry. Since I saw it a few years ago, I would like to figure out whether it has changed. I hope it has in the meantime.

But thank you all for your testimony. Thank you, Madam Chair.

Senator COLLINS. Thank you very much Senator. Again, my thanks to all the witnesses today. This will be an ongoing dialogue. All of us who are so interested in this issue look forward to working with you in the coming months to put together comprehensive legislation on the area of food safety. It is an area that Senator Durbin has done a great deal of work on, and I look forward to joining with him as well as our other colleagues and all of you.

We will continue looking at the remedy stage of this problem in a hearing that will be held tomorrow at 9:30 a.m. in this room. Again, my thanks to all of you. I look forward to working with you. And I thank the staff for its excellent work in this area. The hearing will stand adjourned. Thank you.

[Whereupon, at 12:28 p.m., the Subcommittee was adjourned to reconvene at 9:30 a.m. on Friday, September 25, 1998.]

IMPROVING THE SAFETY OF FOOD IMPORTS—PART IV

FRIDAY, SEPTEMBER 25, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:30 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins and Durbin.

Staff Present: Timothy J. Shea, Chief Counsel/Staff Director; Mary D. Robertson, Chief Clerk; Christopher A. Ford, Senior Counsel; Mary G. Mitschow, Counsel; Don Mullinax, Chief Investigator; Kirk E. Walder, Investigator; Stephanie A. Smith, Investigator; Lindsey E. Ledwin, Staff Assistant; Pamela Marple, Minority Chief Counsel; Beth Stein, Counsel to the Minority; Marianne Upton (Senator Durbin); and Beth Fitzpatrick (Senator Lieberman).

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. The Subcommittee will please come to order. Good morning.

Today, the Permanent Subcommittee on Investigations is convening its last in a series of five hearings on improving the safety of imported foods. As I noted yesterday, the focus of this phase of our food safety investigation is on exploring ways to correct the deficiencies in the food import system.

Yesterday, we heard from the Federal agencies responsible for the safety of imported food and from a representative of the National Academy of Sciences. The Food and Drug Administration, the Food Safety and Inspection Service, and the U.S. Customs Service announced several reforms that they plan in response to the problems revealed by this Subcommittee's investigation. I welcome these positive first steps and look forward to the additional administrative improvements, as well as these agencies' specific recommendations for statutory changes.

As critical as their roles are, government agencies alone cannot provide comprehensive solutions to the problems that plague our food import system. The private sector—from producers to distributors to retailers to consumers—must also be part of any effective program to improve the food safety net.

Americans depend on imports to enrich their diets, especially in areas of the country with short growing seasons, such as my State of Maine. In order for American families to take advantage of the

benefits of consuming five servings of fruit and vegetables a day that have been recommended by the National Cancer Institute and other experts, our food must be safe and affordable. Food safety programs in the United States, in other words, must be effective and comprehensive, but they must not erect needless barriers to impede the import of safe and wholesome foods. The challenge facing us is to strengthen our import system so that tainted products do not reach our dinner plates without stopping the importation of foods that Americans enjoy.

Accordingly, we will hear today from representatives of a number of private groups—industry associations, consumer groups, scientists, and other experts—who have devoted much study to improving our food safety system. It is my hope and expectation that the wisdom and experience of such non-government stakeholders, combined with that of the government agencies from which we heard yesterday, will help this Subcommittee craft comprehensive legislation to improve the safety of imported food.

It is my expectation that such legislation would be introduced early in the next Congress.

My goals are to help ensure that food safety programs are effectively managed, that existing resources are focused on those imports posing the greatest risk of harm to Americans, and that deficiencies in the underlying regulations and laws are remedied.

To this end, we have asked eight industry and consumer organizations to participate in today's hearing. We will hear from the Food Marketing Institute, the Grocery Manufacturers of America, the National Food Processors Association, the United Fresh Fruit and Vegetable Association, the American Public Health Association, the Safe Food Coalition, the American Council on Science and Health, and Public Voice for Food and Health Policy.

I look forward to hearing from our diverse witnesses today and to discussing their ideas on how we can strengthen our food import safety system so that Americans can continue to enjoy a variety of safe and nutritious foods from around the world.

In putting together our witness list today, we attempted to invite groups representing a wide variety of views. There are, however, I have learned, many, many organizations involved in this issue. Due to time constraints, we are not able to accommodate everyone who wished to testify this morning. However, I have sent letters to as many groups as seem to be interested, inviting them to provide written statements for the Subcommittee's consideration. And if there are any other groups that we have forgotten, who are represented today in the audience, we would also invite your input by submitting a written statement.

Without objection, the hearing record will be left open for 10 days, so that all such statements may be included in the printed hearing record and our witnesses have the opportunity to submit any additional information requested by the Subcommittee for the record.

I would now like to call forward our first panel of witnesses. They include representatives of groups associated with various aspects of the food production and food services industries. These witnesses will give us private-sector recommendations for improving the safety of food imports.

Timothy Hammonds is the president and CEO of the Food Marketing Institute, a 1,500-member association representing food retailers and wholesalers and their customers in the United States and around the world.

Dr. Stacey A. Zawel is the director of Scientific and Regulatory Affairs for the Grocery Manufacturers of America. GMA is the world's largest association of food, beverage, and consumer brand companies.

Dane Bernard is the vice president for Food Safety Programs at the National Food Processors Association. NFPA members process and package fruit, vegetables, meat, fish, and special food and beverage products.

Dr. Nancy Nagle is here representing the United Fresh Fruit and Vegetable Association. This is a National Trade Association with over 1,100 members that represents the interests of producers, wholesalers, distributors, brokers, and processors of commercial quantities of fresh fruit and vegetables.

Pursuant to Rule 6, now that you are all comfortably seated, I will ask that you stand and raise your right hand so you can be sworn in.

Do you swear that the testimony you are about to give to the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. HAMMONDS. I do.

Mr. BERNARD. I do.

Mr. ZAWEL. I do.

Ms. NAGLE. I do.

Senator COLLINS. Thank you. Given the wide range and number of witnesses that we have today, I am going to ask that you try to confine your oral presentation to about 5 minutes. If you need a couple of minutes extra to conclude your thoughts, feel free to take them.

Your written testimony in its entirety will, however, be submitted for the record. The lights in front of you will cue you as to the amount of time left. When you have 1 minute left, the yellow light will come on, and then when you see the red light, if you could try to wrap up in the next moment or two.

Mr. Hammonds, we are going to start with you. Please proceed.

TESTIMONY OF TIMOTHY M. HAMMONDS,[1] PRESIDENT AND CEO, FOOD MARKETING INSTITUTE

Mr. HAMMONDS. Thank you, and good morning, Madam Chairwoman. I am pleased to testify for you here today. This is an important issue, and we are very happy to have a chance to express our views. Thank you also for letting us submit our full written testimony, and I will summarize for you.

Let me start by commending you and the Subcommittee for your investigation of the adequacy of government programs to ensure that imported foods are safe. We feel that is a timely inquiry and we welcome it. FMI has a long history of working closely on food safety issues with FDA, USDA, and foreign countries that both im-

[1] The prepared statement of Mr. Hammonds appears in the Appendix on page 188.

port agricultural products and export commodities to us year round.

In fact, I am very pleased to see that Senator Coverdell mentioned in his testimony before this Subcommittee FMI's cooperative effort was carried out with FDA and the country of Guatemala to develop a model plan of excellence to bring their raspberries back into our domestic markets. We are very proud of that program.

Based on our experience, we believe produce imported into the United States is safe, nutritious, and healthy. Yet, your hearings have identified shortcomings in the Federal system for inspecting imported produce, specifically that FDA lacks sufficient resources to give consumers the level of protection they expect. The agency itself has acknowledged these shortcomings. The National Academy of Sciences reached the same conclusion in their report: Ensuring Safe Food From Production to Consumption.

Now that you have identified some problems, let us turn to what we feel might be solutions. The recommendations of the Academy, the President's Food Safety Initiative, and the General Accounting Office provide an excellent framework for improving the inspection system and making better use of existing government resources. Let me point out up front that FMI believes these reforms can be made without costing taxpayers additional dollars and without additional user fees.

First, let us focus just briefly on how we might improve the inspection system. Clearly, the emphasis should be on prevention; that is, keeping contaminated produce from ever entering a country. My written testimony sets forth six basic components of an effective control system. These include a system to evaluate the food safety programs of countries that export produce to America to ensure equivalency with U.S. standards and Federal authority to reject produce shipments from countries with inadequate food safety controls for their exports to the United States.

But regardless of the exact nature of the system put in place, one critical resource need must be addressed. Additional personnel will be needed for inspection and monitoring at our ports of entry. FMI believes this critical need for additional personnel can be met by redeploying to ports of entry existing FSIS in-plant inspectors freed from their current duties by the modern HACCP-based inspection system being put in place for meat and poultry.

We feel there is no question that inspectors will be available. When the new HACCP system is in place, FSIS will no longer need its current complement of inspectors. This will free up thousands of staff hours for use in other areas of food safety. FSIS has not yet evaluated the risks throughout the food system to determine where those resources could best be used to prevent contaminated foods from reaching the consumer. However, your hearings have identified precisely where these resources would be most effective, and that is at our points of entry for imported foods.

FMI believes this redeployment can easily be accomplished in several ways. First, and perhaps most easily, a cross-utilization program between FSIS and FDA. Such a program would allow them to share resources for inspecting imported produce and seafood. The President has already asked his new Council on Food Safety to develop a coordinated budget for the agencies that regu-

late food safety. The creation of this council, complimented by the work of your Subcommittee and others in Congress, sets the stage for such a cross-utilization program. However, should such a program not prove feasible, we could meet the same goal by transferring statutory authority for inspecting imported produce from FDA to USDA or by transferring FSIS inspectors to FDA for reassignment to ports of entry. In our view, a cooperative agreement between the agencies would be far superior to either of these alternatives.

Almost all of the other proposals for improving the safety of imported foods that we have heard require additional tax dollars. Fortunately, the resources and expertise needed to implement this plan that we have outlined already exists within the Federal Government. It is simply a matter of coordinating resources among the affected agencies or, if necessary, redefining responsibilities, as directed by Congress. As a result, the approaches I have outlined would be revenue neutral.

We know this proposal could meet with resistance from both within the government, as well as from industry. Debate is, of course, a part of our natural public policy process. However, debate that fails to reach a constructive conclusion serves no one's interest. As these issues play out in the media, they serve only if continued to raise concerns in the mind of consumers.

The Subcommittee, under your leadership, has raised awareness of the shortcomings of our inspection system for imported foods, and we feel it is now time to move on to a resolution of these problems.

Thank you, Madam Chairwoman, and Members of your Subcommittee for the opportunity to speak with you today on behalf of the members of the Food Marketing Institute.

Senator COLLINS. Thank you very much, Mr. Hammonds. As occurred yesterday, we unfortunately are in the middle of a vote. So I am going to have to recess the hearing for 10 minutes while I go vote. So we will stand in recess for 10 minutes. My hope is this will be the only interruption we have this morning.

[Recess.]

Senator COLLINS. The Subcommittee will resume. I would now like to call on Dr. Stacey Zawel for her comments. If I have mispronounced your last name, please feel free to correct me.

TESTIMONY OF STACEY ZAWEL,[1] Ph.D., DIRECTOR, SCIENTIFIC AND REGULATORY AFFAIRS, GROCERY MANUFACTURERS OF AMERICA

Ms. ZAWEL. Thank you, Senator, and good morning. My name is Stacey Zawel, and I am the director of Scientific and Regulatory Affairs for the Grocery Manufacturers of America.

Today, I would like to talk about the U.S. food supply, which remains the safest and most abundant in the world. Though we are very concerned about imperfections in the system, we should not lose sight of the fact that American consumers safely enjoy more than 750 million meals every day. GMA and the food industry have

[1] The prepared statement of Ms. Zawel appears in the Appendix on page 194.

a great deal at stake in ensuring the safety of our products, and we take this responsibility very seriously.

While the primary responsibility of producing safe food lies with the food industry, FDA and USDA work in cooperation with us to help ensure the safety of our domestic food supply. These agencies must also serve as guardians of the health and welfare of all Americans, especially with regard to the regulation of food imported into the United States. However, to do this, FDA needs no further authority to enforce the law. Imported food is subject to requirements intended to ensure that food is safe, whatever its origin.

Although the Federal Food, Drug, and Cosmetic Act provides FDA with no foreign inspection authority, it does authorize FDA to refuse admission to articles, including foods, that appear to be adulterated or misbranded or that have been manufactured under unsanitary conditions.

The Secretary of Health and Human Services also has the authority to refuse entry to foods that are illegal or subject to restrictions in the country in which they were produced or from which they were exported.

To streamline its import monitoring activities, FDA routinely issues import alerts to its district offices. These alerts identify products and importers that have repeatedly violated Federal law. However, inspection at ports is only one part of a multifaceted strategy to assure that only safe foods are imported into the United States.

To the extent port-of-entry operations can be improved through better management and resource allocation, we would support that effort. It is very important to recognize that inspection alone does not make food safe. In short, we cannot inspect our way to food safety.

GMA believes that the system and scope of FDA authority, parts of which I have described, are fundamentally sound. Rather than merely expanding inspection authority, GMA recommends three steps we believe will more effectively address those food safety concerns, preventing the most significant risk to public health.

First, research must be conducted to identify foodborne hazards and habitats. Second, resources must be allocated to the appropriate prevention programs and, finally, leadership must be asserted in the international standard-setting arena.

Now I would like to expand on each of these areas. First, the agency's responsibility for food regulation must be provided with the means necessary for essential scientific expertise and research. We have to identify and fight true causes of foodborne illness with the right scientific weapons, which can only be discovered through laboratory research and practical testing.

Without proper research supporting our food safety system, regulators will not be able to keep pace with today's manufacturing processes. An effective and credible science-based system complimenting food manufacturers' own safety assessment programs provide consumers with the greatest assurance possible that their food is safe.

Second, the Federal agencies overseeing the food supply need appropriate resources. That means money for scientists, investigators,

state-of-the-art scientific and technological tools, and modern, well-equipped facilities.

Consumers are best served by strong food safety agencies that develop policy based on the best science to build public confidence in the safety of the Nation's food supply. With adequate resources appropriately applied, they will be able to respond to changing dynamics of food safety in a creative and effective manner.

Finally, we must assert strong government leadership in the global arena to stay on course and develop solutions to real food safety problems. Congress needs to provide funding and encouragement to both FDA and USDA to play a more active and influential role at international meetings such as in the Codex Alimentarius.

This means three things: It means supporting workshops prior to Codex meetings to educate our trading partners, especially those in developing countries; it means supporting the personnel needed to coordinate U.S. delegation activities; and, finally, it means building coalitions with other countries who participate in Codex to hasten the process of improving food safety systems worldwide.

The steps I have outlined may seem simple, but they are not simplistic. They require action that is based on science and common sense. GMA stands ready to assist Congress in any way that we can to help further enhance the safety of the food supply in the United States and throughout the world.

Thank you for the opportunity to testify today.

Senator COLLINS. Thank you very much.

Mr. Bernard.

TESTIMONY OF DANE T. BERNARD,[1] VICE PRESIDENT, FOOD SAFETY PROGRAMS, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. BERNARD. Thank you, Madam Chairman, and thank you for the opportunity to be here and provide comments. Thank you for your personal leadership in this issue. I am Dane Bernard, vice president, Food Safety Programs for the National Food Processors Association.

To put our comments into context, I would like to make two preliminary observations, if I may. First, the data on foodborne illnesses do not support claims that imports are inherently less safe than foods produced domestically. Still, we feel that some changes in our system of assuring the safety of imported foods is warranted and NFPA will be pleased to lend its support in identifying appropriate strategies for change.

Second, NFPA does not agree with the impression left by some who have testified that safety of imports is solely the responsibility of the Federal Government. American food companies are not poised with their arms spread wide ready to accept bad product. We have nothing to gain and much to lose in our reputations, our customers, and our sales by such a strategy.

The majority of U.S. food processors know and have confidence in their international growers, producers, and suppliers. U.S. companies conduct more tests, inspect more foreign establishments,

[1] The prepared statement of Mr. Bernard appears in the Appendix on page 196.

visit more growing areas, and provide more information to suppliers than the government could ever do.

America's food processors are very much a part of the food safety-net. Working from this perspective, NFPA supports policies that concentrate on whether food is safe, not on its origins. NFPA maintains that imported foods should be as safe as those produced domestically and NFPA affirms that these foods must meet all relevant U.S. public health standards.

To achieve these goals, we recommend that the United States reach accords with other nations or regions, which rely on determinations of equivalency based on the best scientific information and the application of risk analysis techniques.

These accords should be based on achievement of appropriate levels of consumer protection through application of performance criteria which can be verified by U.S. food companies and government authorities. Since the definition of "equivalent" or "equivalency" are critical to what comes next, we should note that, according to Black's Law Dictionary, they mean just what the word "equivalent" says; equal in value, force, measure, volume, power, and effect or having equal or corresponding import, meaning or significance. In other words "equivalent" and "equivalency" do not necessarily mean identical and are not "the same as," except in the end result.

And I emphasize Dr. Miller's testimony from yesterday, which focused on outcomes of food safety rather than the elements of the system that produced the food.

Now that I have covered a few basics of the NFPA position, I would like to address some specific points from the GAO report. The report recommends that the Federal Government reduce its emphasis and reliance on end-product testing to verify food safety and, instead, promote systems that prevent contamination from occurring in the first place. We fully agree with this conclusion.

As I mentioned a few moments ago, we also agree that all imported foods should be produced under equivalent, not necessarily identical, food safety systems. NFPA cannot endorse, however, legislation that would require other nations to adopt our exact procedures and certainly cannot in any way condone the mandatory imposition of methods that are the same as those in the United States unless no other methods exist to ensure an equivalent level of protection.

To realize these ends, NFPA believes the superior route follows international accords like bilateral Equivalence Agreements, Memoranda of Understanding, Mutual Recognition Agreements, and similar avenues. Voluntary agreements promote cooperation and food safety; mandates only invite retaliation.

When we say "equivalent" or "equivalency," we are talking about looking at the entirety of the plan, the design of the plan. Determinations of equivalence must be based on the best science available, including the application of risk analysis techniques as appropriate to the situation.

Producers must still complete the circle by following appropriate methods, and the country or region of origin must enforce the scheme. For our part, industry and government, we need to trust, but verify. Within this construct, random, relatively frequent end-

product testing may come into play until a record of consistent compliance is established, at which time end-product testing would taper off to periodic, unannounced examinations. The same would apply to inspections in foreign countries under a Memorandum of Understanding or other voluntary accord.

Regarding importing firms, FDA could establish a "three strikes you are out" regulatory threshold where importers with multiple safety-related violations would be targeted for frequent and rigorous inspection, if not out-and-out denial of entry.

For repeat offenders in this category, a permit system could be instituted which stipulates augmented checks on imported food products, much like the FDA's domestic program for producers of canned goods. Bad actors would have to obtain a permit, in other words, from the appropriate agency before they could bring products into the United States and permits would be granted only after the safety of the goods are verified. A "need for permit" classification would terminate only after the importer re-establishes an appropriate level of trust.

Whether under the current scheme or some other arrangement, the FDA, along with customers, must seize greater control over our borders and ports, especially when repeat offenders are uncovered. Allowing rejected products to re-enter at another port cannot be tolerated. Noncomplying imports must be marked or otherwise identified so that end runs fail and those attempting such fraud are dealt with swiftly and effectively.

U.S. authorities must also prioritize infractions and responses according to the risks they pose. The GAO report often cited the example of the Food Safety and Inspection Service ranking incorrect labeling that is not health related on the same par as true health-threatening infractions. This is a ludicrous practice. At the very least, this example displays a disturbing disregard for employing our food safety dollars to their fullest effect.

Finally, the GAO report hints at an accreditation system for laboratories to permit independent food testing by third parties. While the concept has merit, accreditation programs are expensive to establish and maintain. Applying a "three strikes and you are out" system based on random FDA sampling to verify accuracy, compliance, and performance could achieve similar results. Rather than producing a list of accredited labs, FDA could identify those labs that do not produce adequate results.

We agree with earlier comments that additional resources will be needed to further enhance our ability to address potentially contaminated imports. In the near future, resources will be needed to establish Memoranda of Understanding with exporting companies; to verify the accuracy of importer-provided shipping information; and to move repeat offenders from eligibility for the simplified electronic filing to a more intense regulatory strategy.

Also, as suggested by the GAO report, the Food Safety and Inspection Service should modify its automated import information system so that food safety infractions, high-risk products, and unsatisfactory importers can be quickly and accurately identified.

On the need for legislation, NFPA respectfully submits that any legislative initiative, like the Safety of Imported Food Act, should evolve deliberately. We maintain that the FDA already has the

statutory authority to make the changes through regulation that the GAO and others have suggested.

To confirm and clarify what legislation is needed and not needed and as a first step towards coordinating legislative and regulatory initiatives, we recommend FDA outline for the Subcommittee the problems the agency has identified, their current authority to correct those situations, and what regulations it foresees proposing to improve the safety of imported foods.

After receiving FDA's analysis, if legislators, regulators, industry advocates, and food scientists reach a consensus on food safety policy and the FDA demonstrates that legislation is needed, then we should proceed to do so. Our concern is that we have taken a preliminary fire-ready-aim approach in our current proposals that may not produce the most desirable end results.

Madam Chairman, Members of the Subcommittee, this concludes my testimony. I will look forward to your questions.

Senator COLLINS. Thank you, Mr. Bernard.

Before calling on our final witness on this panel, I want to call upon Senator Durbin to see if he has any opening comments he wishes to make.

Senator DURBIN. None at this time. Thank you.

Senator COLLINS. Thank you.

Dr. Nagle, you may proceed. Thank you.

TESTIMONY OF NANCY NAGLE,[1] Ph.D., SENIOR ADVISOR FOR FOOD SAFETY, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Ms. NAGLE. Chairman Collins, thank you for the opportunity to testify this morning. I am Nancy Nagle, Senior Adviser for Food Safety for the United Fresh Fruit and Vegetable Association, and I would like to summarize our written testimony.

I want to remind everyone at the outset of my testimony just how safe fruit and vegetables really are. Of the 3,200 foodborne illness outbreaks reported by CDC from 1986 to 1996, only 31 were related to fresh fruit and vegetables. There is also no definitive data that exists that implies imported produce is a greater risk than domestic.

Your first question was what are the deficiencies in the current food-import process and what can be done to address these problems. In the General Accounting Office's April 1998 report on food safety, they determined that a reliance on port-of-entry inspections cannot provide complete assurance of safety of imported foods. However, we are unaware of incidents of port shopping or other enforcement problems occurring with fresh produce.

It is widely accepted among food safety professionals that the prevention of microbial hazards is far more effective than trying to ascertain and identify and verify the safety of foods after it has been produced and handled. United believes that FDA has ample authority to work proactively with foreign growers, packers, and shippers of fresh fruit and vegetables and their respective governments to prevent food safety problems.

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[1] The prepared statement of Ms. Nagle appears in the Appendix on page 210.

FDA's recent experience in Guatemala confirms the possibility of proactive, cooperative actions in foreign countries to address food safety concerns, but the agency must have the necessary resources to do the job.

United believes that the Federal Food, Drug, and Cosmetic Act provides ample existing authority to FDA to deny the importation of unsafe fresh fruit and vegetables. FDA may refuse admission of food offered for import if it appears, from an examination or otherwise, that a food is adulterated, misbranded, or has been manufactured, processed or packed under unsanitary conditions.

The Act grants FDA the authority to take enforcement action against an imported food based upon far less evidence than is required for the same action against a domestically produced food. FDA need only to determine that an imported food appears to violate the Act. I have attached a more complete description of this authority to the written testimony we submitted.

The greatest constraint to FDA's food safety activities is the lack of resources. The GAO's April 1998 report on food safety describes a situation where imported food entries are increasing at a substantial rate, while FDA's capacity to inspect is declining. We believe that Congress should focus its attention on the underlying issue of resources rather than expanding the agency's statutory authority.

The second question posed by the Subcommittee is: Can regulatory agencies better use their existing regulatory authority to improve the safety of imported food?

In addition to using its automatic detention authority when needed, FDA should pursue three important opportunities to increase the certainty of safe imported foods. These opportunities are the publication of the FDA guidance document to minimize and prevent microbial hazards in produce and the international dissemination of this document; the publication of guidance on the criteria FDA intends to use to evaluate whether or not a regulatory system used by a foreign country to ensure the safety of food is equivalent to the United States; and the pursuit of internationally recognized standards set by Codex Alimentarius for the hygienic production and handling of fresh fruit and vegetables. I elaborate on each of these points in our written testimony.

Finally, the last question posed by the Subcommittee is what other recommendations should be considered to improve the food import process. I encourage the dissemination of the guidance document on good agricultural practices to as broad and multinational an audience as possible. There have also been discussions with various aid and lending agencies to encourage them to support the development of laboratories and other public health infrastructure. If there is greater confidence in the safety of products from a given area, there can also be economic benefits that accompany such confidence. We have also discussed the imported food safety legislation in our written testimony in more detail.

In conclusion, the United Fresh Fruit and Vegetable Association is eager to participate in any responsible effort to enhance the safety of our Nation's food supply. We recognize that foodborne illness is a serious issue, but we do not believe that giving FDA additional

regulatory authority in lieu of needed resources is the appropriate response.

Thank you for this opportunity to testify, and I will be pleased to answer any questions you or other Members of the Subcommittee may have.

Senator COLLINS. Thank you, Dr. Nagle. I do want to start with you to clarify an issue, and you look so happy about it. [Laughter.]

You have testified today that your organization does not support additional authority for the FDA. You do not support proposals for so-called equivalency. Is that opposition based in fears of your members that if FDA moves to an equivalency standard, that it will result in increased regulation for domestic producers?

Ms. NAGLE. It is actually more of a concern that we will not be importing foods at all. One of the things is, depending on whether we define equivalency in a legal manner or in more of a scientific manner, if we look at some of the proposed, or talking about regulations and laws within other countries, we believe that, since we are the top tier in regulations, we could end up with not being able to import food from other countries, where they can produce perfectly safe food, but not necessarily as dictated by their government regulations.

An example would be that if a country does not have the appropriate chlorination systems for their water supplies within their cities or within their municipalities, but a given company that may be producing in that country is doing, is chlorinating their water that is used to wash melons or for their processing, so we do not want blanket disapproval of a country, where there can be definitely safe food coming from that area.

Senator COLLINS. Does your organization think that the equivalency approach that is used for imported meat, poultry, and eggs has worked well or do you have concerns about that also?

Ms. NAGLE. I think I need to talk a little bit more with our legal people there, but we do have some concerns that we could end up precluding imports that would be perfectly safe.

Senator COLLINS. I do not think anyone wants that result and, in fact, I said in my opening statement that I think that is the challenge, is to devise a system that can deal with the fact that we have emerging pathogens to which American consumers are very vulnerable, even if a local indigenous population may have built up immunity to it, that are difficult or impossible to detect through a border port-of-entry inspection.

The reason I raise the issue with you is, in my questions of FDA yesterday, I specifically asked whether FDA officials felt that if we moved to some sort of equivalency system it would result in a whole new layer of regulation for domestic producers because that is not something I want to see. FDA officials were pretty reassuring on that point.

It seems to me that it is in the interests of domestic producers, as well as foreign producers, to have a better system to ensure the safety of food imports; indeed, the safety of all food, because we have had testimony and evidence given to us that consumers do not distinguish as to the origin of fruit that has become suspect. For example, I have been told that when the Guatemalan raspberry incident occurred, which resulted in thousands of people becoming ill

with foodborne illnesses, that people stopped buying raspberries, period.

So it seems to me that it is not in the interests of domestic producers to have tainted fruit come into this country.

Ms. NAGLE. We agree. I have a statement on equivalency that perhaps I could read for us here. I think you have touched upon an important point. I think it is very important that FDA finalize its criteria for determining equivalency.

The agency has the authority to do so, and it would seem to be an important step in allocating inspection resources to the areas that most need it. Beyond the FDA guidance document, we need to be very clear about what equivalency means. I can tell you that, as a food safety professional, there are certain fundamental principles about sanitation that should be universally followed when producing and handling food.

Food consumed in the United States should be produced under these minimum acceptable standards of sanitation, and if that is equivalency, we support equivalency. But if the term is used too broadly in a legal sense, then we could have very significant disruptions. The fact of the matter is that the United States has a set of food safety standards, a regulatory system, and a public health infrastructure that places us in the very top tier of all countries.

If what is meant by equivalency is that countries in Central America, South America, Africa, and Asia are to have systems like ours, then we will not be importing food. People need to understand that we can import safe food from countries that otherwise have poor water quality, inadequate sewage treatment, and a general lack of refrigeration. The reason that this is possible is because those operations that export to the United States use good-quality water, have in place good field sanitation, and use refrigeration.

The fact that a Central American Government may not adequately chlorinate a municipal water supply, does not mean that a melon grower or shipper does not chlorinate, does not have latrines for their workers or that the melons do not have chlorinated roots prior to packing.

We are very concerned that a legal concept of equivalency may be unrealistic, and applied too broadly, and bar the importation of safe food.

Senator COLLINS. Your testimony indicates that, if we go with this approach, we do need to be very careful how we draft the legislation.

Ms. NAGLE. Right.

Senator COLLINS. Your point is similar to one raised by Mr. Bernard, and I just want to clarify for the record that I do not know anyone who is saying that "equivalency" means "identical." It clearly does not. It does not mean "same." It means "equivalent." That is very different. I just want to, for the record, state that because you expressed concern that it might be interpreted to mean "identical" standards to the United States, and I do not know anyone who is advocating that.

You also mentioned, and I think an obvious fact, that your members are not opening their arms wide, I think you said, to welcome tainted fruit. I think that is another obvious statement. On the other hand, tainted products is coming into the United States. We

have had two cases in which thousands of people were sickened with the Guatemalan raspberries and also the hepatitis-contaminated frozen strawberries from Mexico. So this is not a theoretical problem.

Now, I agree with you that the private sector has a very important role to play, and you mentioned that your members actually do inspections, which I commend you for. What actions do you take when you discover a contaminated, unsanitary farm in another country or you discover an unscrupulous importer was trying to pass off tainted fruit or vegetables or other food to you? Do you report that to the FDA or to FSIS or to the Customs Service?

Mr. BERNARD. Thank you for your question. The typical response would be immediate rejection of the product, and usually that happens before it even exits the country of origin. If, for example, poor conditions exist in a growing area or a potential vendor of product that wishes to sell to the U.S. customer, if the auditors on-site decide that that is not someone they want to buy from, it is a market decision. They simply refuse that product.

If there is a consistent problem at port of entry, typically the concept would be to send the product back. It is not out of the question that someone would report that to the government, and that does happen. To give you a conclusive answer to say that that always happens, I am sure I cannot do that.

But if I might go back to the issue of equivalence. Conceptually, I think everybody agrees with the definition of the word, that it does not mean "same as." But you referred to the FSIS system earlier, and the GAO report repeatedly refers to the FSIS system.

Because we do not know the exact level of protection that the sanitary measures that that system utilizes, what we end up doing is looking at the way you do it and the way we do it and coming out with a qualitative judgment that says, "Well, we think it is about the same," and what you end up with is looking at the elements of what we classify as process-based standards; we do it this way, you do it this way. Rather than looking at the level of consumer protection that each process brings to the food. That should be the prime target, and not exactly how you get there.

So I know conceptually we are all talking about equivalence not being the same, but we have not yet determined, on a Federal policy basis, what we mean by equivalence, how we will determine equivalence, and how to go about establishing it within countries or regions that we might want to trade with. So I would say, as a top-line recommendation, that we need to start there with getting our agencies to state their positions and explain the logic. Next, we need to get away from just the logic to the machinery as to how that is going to happen and start filling in some of the blanks and the details of how we are going to go about doing determining equivalence. Thank you.

Senator COLLINS. My time has expired for this round, but I do want to pursue more of these issues with you.

Senator Durbin.

OPENING STATEMENT OF SENATOR DURBIN

Senator DURBIN. Thank you, Madam Chair. On behalf of our colleague, Senator Glenn, who could not make it here today, if there

is anyone in America who does not know why he is absent today, I will remind them he is preparing for the launch October 29 back into space. But he wanted to commend Chairman Collins for her leadership on this issue and her leadership of the Subcommittee during the session and requests that the record of today's hearing remain open so that he may include a written statement on this important issue.

Senator COLLINS. Thank you.

Senator DURBIN. Thank you. First, I would like to ask a fairly general question, very leading I might add, that betrays my prejudice on this issue, and let me just see what kind of response I get from the panel here.

I would like to ask each of you to respond to this question: Do you believe that dividing jurisdiction for safe food inspection in America among at least six different Federal agencies governed by 35 different laws makes our food supply safer, makes obeying the law easier for your members, or serves the taxpayers' needs to avoid added costs of duplication?

Mr. Bernard.

Mr. BERNARD. Thank you, Senator.

The responses that were given yesterday to a similar question, I think, would be our response. Is the current system the optimal system if we are going to design a new system? Obviously, not. I think that the American consumers, industry, and the agencies involved have done a remarkable job in the face of such a confusing system of bringing about a very safe food supply.

We, as well as the agencies who testified yesterday, are awaiting the results of further study. Our organization has continually voiced concern for coordination, in whatever way can be achieved, and we look forward to the further study on the issue.

Thank you.

Senator DURBIN. Mr. Hammonds.

Mr. HAMMONDS. Good morning, Senator.

Senator DURBIN. Good morning.

Mr. HAMMONDS. Thank you for your question. Clearly, we feel that better coordination at a minimum is necessary. As grocers, we are dealing directly with consumers, and perhaps the difficulties surface in the way that is easiest to understand if we think about a time of crisis. Often when there is a food-safety emergency of whatever source, the grocers are the ones that find the TV cameras show up and the reporters are asking questions, and it, when jurisdiction is split, can be very difficult to find a government spokesman willing to come out quickly and reassure the public and establish the exact parameters of the situation we are dealing with.

So, in general, we feel, at a minimum, better coordination is necessary. And certainly we feel that there ought to be a system in place where, in times of an emergency, there is an easy, quick way to find a government spokesman who can reassure, not only the people in the industry, but even more importantly the consumers as well.

Senator DURBIN. Dr. Zawel.

Ms. ZAWEL. Thank you, Senator, for your question.

I think that the—as you described it—litany of the facts and the numbers behind how our system is designed seems rather silly, and

I do not think that anybody would sit down and say, "Is this a great idea? Should we do it if we were going to start to build it that way?" However, we have come this way through history and through adapting to the needs that are there, and so we, in fact, have a system that is exactly as you described, and I think that it deserves to change with the changing needs of the consumers, with the changing needs of food safety, and it has to adapt just like anybody else in this world does with change.

To do so does not necessarily mean wiping out, exactly as you described, the system that exists, but perhaps it means altering the system and how it works through maximizing coordination.

Senator DURBIN. Thank you. Dr. Nagle.

Ms. NAGLE. Thank you for the question, and I think I have got to agree with most of what has been said by my colleagues here. We at United acknowledge that it sounds silly. When you read this litany, it does kind of make you chuckle and say, "If you were doing it, you would not build it that way," but it is already built, and it has actually worked remarkable well, especially considering how disjointed it seems.

We do think, though, that better coordination and more efficient allocation of the resources needs to be accomplished in some way, and we think that really focusing on research and coordinated efforts for education is really a key part of any revamping of the program that needs to happen.

Senator DURBIN. Let me shift the topic from science and food to politics. I know it is kind of far afield from this hearing, but let us try it for a minute.

Senator Collins and I agree on many things. I am not sure we necessary agree on what I am about to say. I will concede completely her point that we need, as you have testified, to revamp our system, to change the laws dramatically, to make certain that it is more effective.

We have had ample testimony to suggest that virtually every Federal agency with any responsibility when it comes to food safety inspection needs to be reviewed and updated. Some of the things that we have been told are just horrifying to think that this kind of bureaucracy, and inefficiency, and incompetency is being tolerated at the expense or danger of the safety of American families and the food that they consume.

Having said that, I also believe that, since we are now embarking on a new era where the American consumers' demand for imported food has grown dramatically, and where the American consumers' demand for safe food is one of the highest priorities, if not the highest priority, imposed on the Federal Government, that it is naive for us to believe that just changing the law is going to accomplish this.

Now, having said that, I think there is a need for more resources here, and more resources to provide more personnel. When you find that there are fewer FDA inspectors than there are ports of entry, then you get an idea of the size of the challenge here.

Now we have engaged here for a while in this testimony, and I have been party to similar testimony at least in the past 12 or 13 years. There is a little ping-pong game going above the table. Let me tell you about the bowling balls that are being thrown under

the table. Most of the organizations represented here—I will just go right out on the limb and say it—hate the idea of a user fee like the devil hates holy water.

The thought that your association members would have to pay a user fee for inspection is something you do not want to suggest they would embrace, in fact, they despise the idea. They do not want to pay for it. And so what are our alternatives? If we need more resources—I believe we do. Some may argue we do not—if we need more resources, and if we are not going to impose a user fee on the people who are going to have their product inspected, then the alternative is to turn to the Treasury and say, "Appropriate more money."

Well, we know better because we are in an era of balanced budgets, and there is just not that much money to go around. And year-in and year-out, for as long as I can remember, administrations—Republican and Democrat—have talked about user fees as the way out and nothing has happened. It is a nonstarter.

A long introduction to what I am about to say. The reason why I think we need to move to one agency, avoiding this duplication, coordinating these services, is that we can generate more service out of the people that we have, and each of you are kind of edging into that.

Mr. Hammonds, in your testimony when you talked about moving USDA personnel into areas that might be more directly involved in food safety inspection, when each of you talks about coordinating FDA and USDA, you are heading in my direction. We are really reaching the point I think we all know we have to reach. We need one agency that is not overlapping, that is not duplicating, that has a set of scientifically sound principles that your members can live by.

I think, honestly, I would like to commend to each of your organizations to think about this again, and if from just the most selfish interests say this may be the only way to avoid a user fee is to put one agency in place and take all of the personnel involved and put them out doing their job in a more scientific and sensible way, so that your members know what the rules are and the consumers are getting a job well done. That is my speech.

Now, having said that—if anybody would like to comment they are welcome to. I know this is questions and answers—let me ask you about the problem of equivalency, and let me go back to what Senator Collins said. She is right. We are not talking about identical standards.

Let us get down to basics here. If we are talking about the contamination of water, if we are talking about terrible things which occur when you do not have sanitary standards around those who are handling food and picking crops in other countries, we might respond to it in the United States by saying we need portable toilets, we need someplace where an employee can wash their hands. What are they going to do in Honduras? What is the answer there? What is the equivalency there? And that I think is the real question we ought to consider.

I think we need to move towards some sort of equivalency. In fact, we are almost bound to by our trade agreements, if we want to have it enforceable. But I want to make sure we follow through

on this. Are we on the same wavelength here; that we might be talking about different approaches with the same goals in mind, in terms of sanitation, which appears to be one of the most basic concerns here.

Dr. Zawel.

Ms. ZAWEL. Well, I think that equivalency is the appropriate term to use. I think what you said is that our goal in achieving equivalency is exactly the same. The approach is what I would call the devil is in the details, and that is where our concern would be.

I would describe, in my mind, without having thought in-depth about how we achieve the equivalency, I think that is a very complex question that deserves a tremendous amount of thought, but I think that what we want to see is not how many toilets are in Honduras and how many are in the United States but, in fact, do we have an equivalent food safety infrastructure in Honduras and in the United States. But I do not want to go so far as to conflict with Dr. Nagle, who appropriately stated that we cannot blacklist an entire country just because there is a perception that everything coming from that country is, in fact, being produced in an unsafe manner. I do not think that that is the case at all, but there are silos within countries that can achieve equivalence and that we should look at it that way.

It is not necessarily a direct answer to how we do it, but I think that equivalency is certainly the goal that we are all interested in.

Senator DURBIN. Mr. Hammonds.

Mr. HAMMONDS. If I might comment on both of your issues. First, as to resources, we provided what we feel is a revenue neutral way to bring substantial resources to bear on our ports of entry. You prefaced your remarks by saying it was a political issue. Fortunately, the single-agency issue is one you ultimately have to make a judgment on and we do not. But we feel that there certainly is a chance that this could be done with a cross-utilization agreement. And while we are debating the single-agency issue, perhaps, that is a reasonable way to get started and get started quickly.

So we think that is a way to be able to dramatically improve our monitoring at ports and not have to go to user fees or tax dollars.

On the issue of equivalency, let me just draw on the Guatemala example very quickly, if I might. I think the important thing here is it is not a one-way determination. This can easily, and should, be a dialogue.

In the situation with the Guatemalan raspberries, the country of Guatemala came to Food Marketing Institute I think because we were not directly involved in buying products, but represented the end consumers and their expectation that the product was going to be safe. And we worked very closely with the country, with the growers in their home country, and with the Food and Drug Administration and, together, worked out a very reasonable solution.

So I think if this is undertaken as a dialogue between the importing countries, and the countries' own producers, and our Federal agencies, that a very reasonable solution can be worked out, and often without having to involve the lawyers as the final arbiters here.

Senator DURBIN. Thank you. Thank you, Madam Chair.

Senator COLLINS. Thank you, Senator Durbin.

Dr. Zawel, I want to follow up on Mr. Hammonds' idea for a redistribution of resources from FSIS to FDA port-of-entry inspections. Could you comment on whether you agree with his proposal in that area.

Ms. ZAWEL. Well, our comment, also in the context of responding to Senator Durbin's statement, which is that a single food safety agency is perhaps—that was his recommendation. I think, historically—as we have historically built this regulatory system that we have, we have historically set up silos that exist, and to break down those silos is what I mean by coordination and maximizing coordination, and efficiency, and effectiveness, and one of the mechanisms to do that would be to redistribute the resources that we have within each of these silos, if you will, to the changing needs of food safety.

And so, perhaps, that is one recommendation that certainly would make some sense.

Senator COLLINS. Mr. Bernard, I want to go back to the point that you made about the accreditation of labs and that you felt this would be a needlessly expensive undertaking. It was GAO that first raised concern about the lack of control that the FDA had on the samples that were taken from suspect shipments and the lack of control over labs. Again, FDA's process contrasts with FSIS, which does use accredited labs.

If FSIS is able to use accredited labs, why are you concerned that it would impose a new excessive cost on the system for FDA to adopt the same approach?

Mr. BERNARD. Thank you, Senator, for the question. FSIS typically uses its own laboratories for testing samples and, obviously, they have a great deal of confidence in those results because of the controls in place. FDA has obviously its own microbiological capabilities. But to expect their laboratory to keep up with such a volume of samples that might be derived from intensive sampling of imports seems impractical to us.

The alternative would be to use accredited private laboratories. Our concern is that, while that is a strategy that is certainly worth looking at. There are private organizations looking at (and almost finalized) in putting together a program to accredit private laboratories, that could be capitalized on. But whether that would match with what the Federal expectations are, what consumer expectations are is a question mark.

An accreditation program, I think, with government intervention would involve check samples, would involve scripting out exactly what laboratories are supposed to do, and would involve on-site inspections, further stretching inspectional resources.

It should be a topic of discussion as to whether it is worth that kind of expenditure or whether there is not something else that we could do to achieve the same end without having to go through that many hoops and spend further Federal resources.

Our proposal is that, as we have done for years in the canned food industry, after some time of working with an organization, the government knows who they can trust and who they cannot trust. In this case, the government should pull its own samples for verification, and if they disagree with laboratory results submitted by a laboratory and that pattern is established, then you can as-

semble a list of those who are just not producing the right kind of results.

So I think that our proposal merely is a consideration whether there is a less expensive, less resource-intensive way that we can achieve the same assurance. If not, then obviously we are just trying to look at all options. We are proposing that as a different option.

Senator COLLINS. I appreciate your clarification on that issue. Would you agree that the current system does allow for avoidance of the FDA's process by an unscrupulous importer?

Mr. BERNARD. Based on the GAO's report, sure. We can see that there is room for improvement in the system, not only in the way the samples are collected, but in the way the laboratory analyses are run. I think probably the main concern, based on some of the conversations we have had, is just security of the samples, making sure the right product gets sampled and that there is no opportunity or little opportunity for firms to substitute good products for bad when the samples are to be taken.

Senator COLLINS. Thank you.

Mr. Hammonds, I want to switch gears and ask you about an initiative that I understand FMI has undertaken called your Total Food Safety Management project. It is my understanding that you are working with a firm in Westbrook, Maine, called IDEXX, which has been in the forefront of developing some food safety tests. Could you tell us a little bit about your project and whether you think it might be a useful model.

Mr. HAMMONDS. Yes, I can. The project is really based on the general principles we have been talking about here, and that is focusing on prevention, focusing on risk analysis so the resources can be put in the right place at the right time.

What we are doing is developing for our supermarket members models to maintain the safety of critical food products in the store. So our first initiative here was to look at the kind of products we handle and make a determination of where we thought the resources would be best allocated to protect the products and identify a half-dozen of those. They would include cut produce, cooked chicken, and ground beef as three of the specific products we look at.

Then we recruited volunteer supermarket companies to work directly with the group in Maine. We put their scientific experts in the stores to make a determination of the critical control points; that is, what points in the system of delivering this product from the consumer, all of the way from receiving from our suppliers and working with our suppliers on the kind of standards for products that we buy from them might entail, and then they are in the process now of identifying those critical points where training, and recordkeeping, and monitoring would be most effective.

As they identify those, they will develop specific training modules for in-store personnel that people can understand and implement without having to be a food safety technical expert. We then will test that system in a real-world setting and monitor the end product. And once we determine the control programs, the training programs, and in-store monitoring are effective, we will make that available to the entire industry.

So that as we train our in-store personnel in each of these departments, we can direct them to the critical control points where they will be most effective and give us the highest quality and safest products for consumers.

So it is a very specific product-by-product hazard identification and training program designed for supermarket employees.

Senator COLLINS. Thank you. I think that does have a lot of promise, and it is part of my belief that each of us has a role to play in improving our food safety system, and I appreciate knowing of your efforts.

I just have one other question that I want to ask all of you, just to make sure we are clear on the record. I believe I have heard this morning three out of four of you oppose any additional authority for the FDA in this area, but I just want to make sure that I understand whether you are talking about just the equivalency or across-the-board.

I also want to make sure, starting with Dr. Nagle, in view of your comment on port shopping, that we share the evidence that we have that there is extensive port shopping going on by unscrupulous importers, but I will have the staff share that evidence with you.

But I will start with you, Dr. Nagle. Specifically, do you support any additional authority for the FDA to ensure the safety of food imports?

Ms. NAGLE. At this point and, again, I am not a lawyer, but United's position is pretty clear. We believe that they have sufficient authority under the current Act to deal with denying entry for an imported product. And if we use the Guatemalan example, it also shows that they have the capability to go to a foreign location and to work with them there and inspect the fields. So, that it does not seem that there is anything in the statute that prevents them from doing that now, and, therefore, they do not need any additional authority granted to them.

Senator COLLINS. Dr. Zawel.

Ms. ZAWEL. I would certainly agree. As I said in my statement, we believe that FDA does not need any new authority to assure that foods coming into this country are safe. In fact, what they do need is a reassessment of their current activities, a reassessment of resources and more coordination to increase their effectiveness.

Senator COLLINS. Mr. Hammonds.

Mr. HAMMONDS. Well, we believe you need an effective control system and you need the proper resources to carry it out. If the FDA were to identify additional authority that was needed and the scientific community could agree that that would, indeed, be beneficial then we would not oppose that.

Senator COLLINS. Mr. Bernard.

Mr. BERNARD. Thank you.

I think Mr. Hammonds said exactly our position. We remain today convinced that there are changes that need to be made. The Senator mentioned earlier that there are documented outbreaks that cannot be denied. There are improvements necessary. We do not feel today, however, that all of the existing options have been fully explored, so, we remain, at this point, unconvinced that there is a need for additional legislated authority.

Thank you.

Senator COLLINS. I thank you very much for your testimony this morning. The debate on that issue will, obviously, continue with our next panel. It's fascinating to me to hear your testimony when FDA and GAO believe FDA needs additional authority, but it is an issue I raised with FDA officials yesterday that they were able to take effective action in the case of the Guatemalan raspberries.

But we will see, as the debate continues, where this comes out.

Thank you very much for your testimony.

The next panel of witnesses will provide the Subcommittee with recommendations from consumer groups and public health officials. Dr. Richard Levinson is the Associate Executive Director for Programs and Policy of the American Public Health Association. This organization is comprised of over 30,000 individual members and 20,000 additional State and local affiliate members and represents more than 75 disciplines in public health and related fields.

Carol Tucker Foreman is representing the Safe Food Coalition, an umbrella group of consumer, public health, senior citizen and labor organizations that works to educate the public about the hazards of foodborne illnesses.

I would also note that Ms. Foreman is a former staff member of this Subcommittee, I learned last night, in one of her first jobs after graduate school. So, it is a great pleasure to welcome her back to PSI today.

Dr. Ruth Kava is the Director of Nutrition at the American Council of Science and Health, a consumer education consortium concerned with issues related to food, nutrition, chemicals, pharmaceuticals, the environment and health. This organization is led by a Board of 250 physicians, scientists and policy advisors.

Robert Hahn is here on behalf of Public Voice for Food and Health Policy. This is a national nonprofit research and advocacy organization that looks at food and agricultural policy from a consumer perspective and promotes a safer, healthier and more affordable food supply.

Pursuant to Rule 6, I am going to ask you to stand and be sworn in. Would you raise your right hand?

Do you swear that the testimony you are about to give, is the truth, the whole truth, and nothing but the truth, so help you, God?

Mr. HAHN. I do.

Ms. FOREMAN. I do.

Dr. LEVINSON. I do.

Ms. KAVA. I do.

Senator COLLINS. Thank you.

As for the previous panel, I am going to ask that you limit your oral testimony to 5 minutes. If you need an additional couple of minutes to finish up, however, feel free to take that time and the green light, yellow light and red light will help guide you.

I am going to start with you, Dr. Levinson.

TESTIMONY OF RICHARD LEVINSON, M.D.,[1] ASSOCIATE EXECUTIVE DIRECTOR FOR PROGRAMS AND POLICY, AMERICAN PUBLIC HEALTH ASSOCIATION

Dr. LEVINSON. Thank you, Madam Chairman.

My name is Richard Levinson and I am the Associate Executive Director of the American Public Health Association and I am very grateful to present our point of view on how we can help ensure the safety of the food supply for the American public.

I wish to begin by emphasizing that we strongly believe that food safety is a major public health problem in the United States. We concur that the food supply in this country may be, indeed, the safest in the world but despite lack of solid information about the incidence of foodborne illnesses, our estimates or the estimates that are provided indicate that millions of such cases of foodborne illness occur each year in the United States, and that some of them, perhaps a small number, but some of them do lead to death and disability.

The whole process of foodborne illness is certainly a major cost to the United States in terms of medical care and disability resulting from such illnesses. We cannot say that at this time that imported food is necessarily less safe than domestic food, but we certainly know very clearly that imported food has been responsible for a number of recent outbreaks. The *Cyclospora,* the Hepatitis A and Salmonella instances indicate this very clearly.

In view of the fact that the volume and percent of imported food is steadily rising in the United States, our risk-based approach suggests that we should be very much concerned about imported food and its safety.

Looking at the ways in which we might improve the safety of imported food, I have to begin by stating that we will never be entirely successful in that effort until our own system of guaranteeing domestic food safety has been improved upon and made basically more optimal.

The National Academy of Sciences in its recent publication, which is entitled, ''Ensuring Safe Food From Production to Consumption'', has pointed out that there are some 12 agencies in the United States that are responsible for food safety and that they operate under 35 different legislative statutes, some of which are contradictory in their scope.

The result has been that there is a great deal of fragmentation, duplication, overlap and even outright conflict in the enforcement of food safety activities within the United States from the Federal Government point of view. Furthermore, the Federal approach rarely gets down to the State and local individuals who are also trying to monitor food safety and it has rarely involved the public to the extent that it should since the public is the key factor in this whole equation.

Looking at the Federal organizational approach to food safety it is quite clear that the Department of Agriculture and FDA are the two principle agencies but the other 10 cannot be disregarded. These two agencies also overlap and conflict in many of their ac-

[1] The prepared statement of Mohammad N. Akhter, M.D., MPH, was submitted on behalf of the American Public Health Association, appears in the Appendix on page 221.

tivities domestically, and the famous example of the pepperoni pizza in which we have two agencies inspecting one product, often at the same time, and certainly creating a certain amount of confusion not only for the makers of pepperoni pizza.

If we look at their activities internationally, it is perfectly clear and apparent that they are approaching control of food safety under an international basis in a totally contradictory manner. The equivalent authority that FSIS, from the Department of Agriculture, has is perhaps not entirely perfect but it seems to be infinitely preferable to the point-of-entry approach of the Food and Drug Administration.

The FDA simply does not have the person power or the ability to monitor every point-of-entry by which food might enter the United States and current estimates are that it monitors less than 2 percent of these points-of-entry, which is grossly inadequate.

You have dwelt in your previous testimony on the inadequacies of assuring control of food that is being embargoed for inspection by the FDA by the use of questionable laboratory procedures and laboratories to monitor it, and by a whole host of other issues that arise in this point-of-entry type of situation.

What do we recommend be done about improving the situation? Now, there are many, many aspects of this. Certainly the science has to improve, certainly the methods of inspection and surveillance need to be extended, but we think that the whole thing could be significantly improved, including all of its aspects, by developing a single Federal agency which has the total authority and responsibility for all Federal activities in food safety, both domestic and international. This agency should cover all of the functions that are related to food safety. It should have the resources necessary to carry it out. And, most important of all, it must have the legislative authority to be effective.

Until this happens we are convinced that patchwork types of solutions, which have been employed in the past in attempting to make agencies more equivalent in their approach to international or domestic food safety issues, simply will not work. I notice that my time is up and I can further expand in the question period on this. But, I think that I do want to emphasize we feel this is the most important thing we can contribute to the debate, the support for a central agency.

Senator COLLINS. Thank you very much, Dr. Levinson.

Ms. Foreman, would you, please, proceed?

TESTIMONY OF CAROL TUCKER FOREMAN,[1] COORDINATOR, SAFE FOOD COALITION; ACCOMPANIED BY CAROLINE SMITH DeWAAL, DIRECTOR OF FOOD SAFETY FOR THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST ON BEHALF OF THE FOOD SAFETY COALITION

Ms. FOREMAN. Thank you. Good morning. I am here as the Coordinator of the Safe Food Coalition, a group of consumer, public health, senior citizen and labor organizations who have worked together since 1986 to improve the Nation's food safety system. The coalition was instrumental in persuading the Federal Government

[1] The prepared statement of Ms. Foreman appears in the Appendix on page 229.

to revise the 100-year old meat and poultry inspection system. My own interest in this issue stems from my service as Assistant Secretary of Agriculture for Food and Consumer Services during which time my responsibilities included meat and poultry inspection.

My testimony today was prepared by and is based on research done by Caroline Smith DeWaal of the Center for Sicence in the Public Interest. My oral statement is taken from that.

Our coalition appreciates very much both the vigorous and meticulous work that this Subcommittee has done in investigating and documenting the problems with the safety of imported foods. You have revealed a number of weaknesses that are serious and have to be resolved.

Neither our domestic nor our imported food supplies are safe enough. It is true that millions eat safely every day but it is also true that millions get sick every year and that thousands die from foodborne illness. That toll can be and should be reduced.

We are more aware of problems with imported foods now because imports have expanded so dramatically. Thirty-eight percent of our fruit now comes from other countries, as do 12 percent of our vegetables and half of the seafood we consume.

That is not a bad thing. We live in a world market. I love as an individual, and its clear consumers all over the country love, having access to food that comes in from other places. It is nice to be able to have that summer fruit in the middle of the winter here. But it is acceptable, in fact, it is reasonable that we will demand some assurance of safety in those foods.

While food imports are expanding, the Food and Drug Administration's resources allocated to inspecting them are declining. In 1990, they physically inspected 8 percent of the imported food; today they will physically inspect only 1.6 percent. Inadequate inspection has consequences.

CSPI has identified 14 outbreaks of foodborne illness since 1980 associated with imported food—cantaloupe, crab meat, tuna, cheese and strawberries are among them. Countries of origin include Ecuador, Portugal, Israel, the Netherlands, and Guatemala.

I would like to make some suggestions about how to improve the safety of imported food. The Congress can start right now this week—by starting to provide FDA with some additional resources to do the job that needs to be done. It can improve the Agriculture Appropriations Act Conference Report by approving an increase of $68 million in the President's Food Safety Initiative. That would give FDA an additional $26.7 million for new import inspections.

The agency needs those resources and they need them, I think, immediately. I think your hearings and investigations indicate that over and above all other things.

We need to give FDA the authority to do the job. And you have several pieces of legislation pending before the Congress now. S. 1707 and H.R. 2052 provides specific authority to reject food from countries that have denied FDA inspectors access to review growing and processing.

H.R. 4080 would provide a modest fee to importers in order to increase border inspections and begin to develop real time microbiological testing.

H.R. 3676, the Consumer Food Safety Act, would require both domestic and foreign food processors to register with FDA and requires regular inspections of all high-risk processors. We believe that is absolutely essential for FDA to have some equivalency authority similar to that of USDA.

I have had experience with administering USDA's system. It works reasonably well and I would be glad to answer questions with regard to that if you would like me to later.

The second thing you can do is to rationalize and unify the entire food safety system as recommended by the National Academy of Sciences. It is really essential to revamp the statutes, to have one unified food safety law and avoid different authorities, requiring different things.

The basic goal of those should be to protect public health and to allocate resources according to the risk to public health. We need one Federal official with the responsibility and the authority to do the job.

Again, I can tell you from a personal perspective that the present system just does not work. And if you ask anybody who has ever had responsibility for administering either meat and poultry inspection of the Food and Drug Administration, they will tell you it is a miserable way to achieve an effective, efficient food safety system. At least two Members of your Subcommittee support the creation of a single food safety agency.

My time has expired. I do want to say one last thing. I have some serious concerns about GAO's proposal for redeploying resources, $271 million, from FSIS to FDA and if the opportunity arises I would like to comment on that.

Senator COLLINS. If you would like to comment right now on it, feel free to do so.

Ms. FOREMAN. OK. Thank you.

I am not a defender of the old-fashioned way of inspecting meat and poultry. I have spent a lot of time trying to change it. The Department of Agriculture has now taken that on and is trying to do away with this 100-year old system and introduce a modern system.

We have to be careful that we take reasonable and rational steps to get from here to there. It is a 100-year old system. There are 6,000 plants out there. Some of them are very sophisticated and some of them would shock you at their lack of sophistication. They rely on the inspector to walk in every morning and tell them to wash the equipment. If the inspector fails to say that, they do not wash the equipment.

Public health is at stake. We have to move carefully and judiciously from that old system to the new system. There are 7,200 inspectors and 6,000 plants. I am afraid if we say, all right we got a new system. Let's pull everybody out of these plants and send them over to the Food and Drug Administration, we may have terrible negative unintended consequences.

I am perfectly prepared to see a plan that lays out a time certain for beginning to move away from the old inspection process. I am prepared to redeploy resources as data come in that show the new system works in reality as well as in theory. USDA has those studies underway now. I am confident that they are going to show that

the system is working. But I am afraid that because of what the GAO recommended, inspectors will be pulled out of plants and public health will suffer.

Senator COLLINS. Thank you.

Ms. FOREMAN. Thank you.

Senator COLLINS. Dr. Kava.

TESTIMONY OF RUTH KAVA,[1] PH.D., R.D., DIRECTOR OF NUTRITION, AMERICAN COUNCIL ON SCIENCE AND HEALTH

Ms. KAVA. Thank you, Madam Chairman.

The American Council on Science and Health thanks the Subcommittee for the invitation to testify here today. And we would like to basically reiterate some of our written testimony. First of all, between 1983 and 1997, according to the GAO report, there were at least 17 outbreaks of foodborne illness in which imported foods were suspected, if not proven, sources of pathogens.

But it is not clear, according to some work done by USDA, that imported foods pose any greater risk to the health of the American people than do domestic counterparts, simply because the information is not really there. It is fragmentary. Not all outbreaks of foodborne illness are traceable. We do not know exactly where—although the Mexican strawberries, obviously, came from Mexico, they were contaminated with Hepatitis A but they were processed in the United States. So, my understanding is we really do not know where that contamination occurred.

This kind of issue is also a problem in determining exactly where the onus of responsibility lies for certain types of foodborne illness outbreaks.

As has been noted here by several people this morning, the importation of foods and food products has increased substantially. In 1996, imported foods accounted for 21 percent of domestic fresh fruit and vegetable consumption. And this is probably going to increase. As has also been noted, we like having our fruit and vegetables in the middle of the winter that we cannot grow here ourselves.

Now, the GAO report certainly indicates that there are major discrepancies between the responsibilities of the FDA with respect to maintaining imported food safety and the resources which that agency is given in order to perform that function. The FDA faces an increasing volume of imports but has a static number of inspectors, insufficient financial resources and we feel a lack of legal authority compared to that granted to USDA.

We, therefore, would recommend that these discrepancies be eliminated and that Congress take steps to enable FDA to perform its regulatory functions more efficiently. With respect to the question of equivalency, we see it as a positive thing that FDA be granted some sort of authority to ensure equivalency in the scientific sense. I know we have discussed the definition of the word here this morning. And that perhaps the timing with which this equivalency requirement be enforced be flexible to allow us to take into account the differential abilities of trading partners to come up to speed.

[1] The prepared statement of Ms. Kava appears in the Appendix on page 241.

FDA has already established memoranda of understanding with some countries and that process could continue and evolve into some sort of an equivalency situation.

We also feel that all existing food safety oversight agencies should support and expedite the use of existing technologies such as food irradiation that we already have approval for but which are not yet being used. Partly, we understand because there are bureaucratic problems with getting guidelines set up so that people can actually go ahead and use these technologies.

In terms of the efficiency of use of the different agencies, we see this as one way in which efficiency could be improved. We do have existing technologies that could help improve food safety and we are not using them. We should be using them. We would like to encourage that.

We would also like to encourage focusing on proven health risks in Congress' efforts, not those that are based on hyperbole. I noted in the GAO report, some of the testimony there emphasized that FDA has said for many years that the greatest risk in terms of foodborne illness are microbial pathogens. And, yet, what you hear out there from consumers and what we get questions about, not infrequently, are things like pesticide residues. To my knowledge, pesticide residues have not been the proven cause of any major outbreak of foodborne illness. It is a constant fear but there does not seem to be good data supporting that.

Finally, we also feel strongly that there needs to be more education effort to tell the consumer about what the real risks of foodborne illness are, more education in terms of how they need to handle and prepare foods in order to avoid foodborne illness, and perhaps just as importantly, to educate the public to an understanding that there is no zero risk. That there is always some level of risk and the government is not going to save them from all possible foodborne risk possibilities. Thank you.

Senator COLLINS. Thank you, Dr. Kava.

Mr. Hahn.

TESTIMONY OF ROBERT HAHN,[1] DIRECTOR, LEGAL AFFAIRS AND RESEARCH, PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Mr. HAHN. Thank you.

Madam Chairwoman and Members of the Subcommittee, good morning. My name is Robert Hahn, Director of Legal Affairs and Research at Public Voice for Food and Health Policy, a nonprofit consumer research and advocacy organization that seeks to ensure a safe, nutritious and affordable food supply.

To avoid being unduly repetitive, let me just say that we agree that the FDA system for ensuring the safety of imports is clearly in need of reform and that many of the needed reforms will require legislation and additional resources.

The first order of business should be for FDA and its partner, the Customs Service, to improve border inspection and to eliminate the many opportunities for unscrupulous importers to commit fraud. Some of these measures FDA and Customs can take now without

[1] The prepared statement of Mr. Hahn appears in the Appendix on page 244.

Congressional action and, as we heard yesterday, the two agencies are moving to do so.

For example, Customs should increase the civil penalties for food safety violations. FDA inspectors and not the importer should collect all samples for lab testing, and all testing should be done by either an FDA lab or an accredited private lab. And FDA and Customs must find a way to ensure that rejected shipments are reexported or destroyed.

Other needed measures will require legislation. We believe that Congress should authorize FDA to require the registration of all food importers and to charge them a nominal registration fee. Second, FDA should have the authority to require the use of accredited laboratories.

Third, Customs should have the authority to require importers with a history of violations to use independent bonded truckers and warehouses at their own expense. Fourth, Congress should give FDA the authority to stamp rejected shipments with the words, "Refused Entry." And, fifth, Congress should give FDA the authority to levy civil fines. FDA should not have to rely on Customs, an agency with different priorities, to collect fines for food safety violations.

While improving border inspection is important, border inspection has serious limitations as a way of ensuring the safety of imports, as we have already heard.

Given the increasing volume of imports and the resource constraints on the FDA, FDA will probably continue to inspect only a very small percentage of imports. And even when a shipment is inspected and a sample taken for lab testing, it is very difficult to catch contamination which may be randomly distributed in the product, and certain types of pathogens, such as viruses and parasites, are very difficult to detect at all.

Giving FDA equivalency authority is the long-term solution to the problem of unsafe imports. If we are going to import food from around the world, we ought to know something about the system under which it was produced. With equivalency authority, FDA could require exporting countries to open their food safety systems to FDA review and if FDA knows that an exporting country's food safety system is a disaster waiting to happen, FDA should have the authority to ban its imports without waiting for a major outbreak of foodborne disease.

Finally and equally important, FDA needs additional funding to perform its responsibilities effectively. It is clear that FDA will need significant additional funding if it is to ensure the equivalency of foreign food safety systems while maintaining an appropriate level of inspection at the border.

Thank you for this opportunity to share our views, and I would be happy to answer any questions.

Senator COLLINS. Thank you very much, Mr. Hahn. And thank you all for your helpful testimony.

After listening to five different days of testimony and doing a lot of work in this area, it seems to me that there is a consensus that we need to fix some of the smaller administrative problems. For example, FDA ought to be marking or stamping shipments, "Refused

Entry," so that they cannot so easily be entered into the American market place.

And we need better fines so that it is not just a cost of doing business if you get caught violating the law. We need, perhaps, to give more authority to agencies to impose civil penalties, so that there is a greater range of penalties.

Then we come to the harder issues. And it seems to me they break down into three categories. There are those who believe that the only way to improve our food safety system is through a dramatic organizational change. Senator Durbin has worked very hard over the years in favor of advocating a single food agency and Dr. Levinson endorsed that today, as have others.

There are others who believe this is really a resource issue. And that the problem is that FDA only inspects fewer than 2 percent of all shipments. And that you really need to have more resources so that FDA can do more inspections and that it is a mismatch of inspections versus the volume of imported goods.

The third category of people argues that we really need a whole new system, that we are never going to be able to catch up to the problem through ports of entry inspections and that we need to go to an equivalency system and get at the root of the food safety issues.

I am beginning to think that we probably need to do some of all three. I am not convinced yet, although I may be ultimately, that we need an entire new organizational structure and I wonder what that does if you do not solve some of the underlying problems with equivalency. But, clearly, we have established a record that suggests that there are very severe coordination problems because we have so many agencies involved.

I would like to start with Dr. Kava and then go down the row here, and ask your judgment. Is this primarily an organizational problem, is it primarily a resource problem or do we need a new system or is it a combination of all three?

Ms. KAVA. It is probably, we would think, a combination of all three. Although in terms of sort of junking the whole system and starting over again, I am not sure that I see how that would speed up the improvement of food safety because the simple reorganization process, itself, would be lengthy and complex.

It would seem that resources are a significant issue, especially as outlined in the GAO report, and we would support the Food and Drug Administration being given appropriate resources in order to carry out its mandate.

Again, as far as equivalency goes, FDA, itself, has apparently questioned the need or it sounded almost in the report was concerned about having mandatory equivalence. We would think that would be necessary eventually. That FDA and FSIS should not have disparate levels of authority for ensuring the safety of foods.

So that we would be in favor of it but we think also that this could be worked out to be as painless as possible for trading partners by working perhaps through the Codex Alimentarius that the United States should take a leading role in trying to effect those changes in that way too.

I think there are mechanisms by which equivalency could be established and at this point, it sounds good to say, well, we have 12

agencies and 35 laws, so, let us junk that and have one system. But that does not—it sounds good but it is not clear to us, at least yet, how that would definitely improve things because with one agency you could also have a stranglehold over a lot of different systems that might not benefit all of us equally well.

Senator COLLINS. Thank you.

Dr. Levinson.

Dr. LEVINSON. Yes, thank you.

Certainly there are resource issues and whether you have a new system, one agency or multiple agencies, the resource issues will continue. More resources have to be put into the whole process of guaranteeing food safety.

I think the equivalence issue for the international scene has really been settled. I do not know of anybody that supports the point-of-entry approach that FDA now uses over the equivalence issue.

I think the problem comes up in defining equivalence, and we have heard several definitions today. The one I prefer which I did not hear is that it is exactly the same as the United States' system. I know that cannot be achieved easily but it is the goal towards which we have to work.

As far as revamping the system, I think that this is necessary because of conflict in the legislation and in the cultures of the organizations that implement that legislation. But I think that any reorganization or any attempt to set up a new agency would base it on science and on risk analysis and on effective surveillance. So, however this is done, those three principles have to be guaranteed.

And since these things are honored more in the breach than in practice, enforcing them would set up a new agency or new approach. I have already stated that I think there needs to be one agency.

My principle reason is that unless you have that you are going to continue to have conflict between organizations involved in terms of their culture, their history, their approach to the world, and although these various approaches may be individually valid, you need one solid approach if you are going to effectively regulate the food industry. So, I think there has to be one agency.

Senator COLLINS. Ms. Foreman.

Ms. FOREMAN. I think that you scratched the itch of the import problem and found that underneath it there is a much bigger problem. I think that is what is happening here.

The problems that we have with the safety of imported food is a reflection of a law and an agency structure that were designed for another time when there were not international markets of the kind that there are now and, certainly, when the health risks were different.

Carcass by carcass inspection was set up when the same things that made animals sick made human beings sick. That stopped being true a long time ago, but we have updated the law to deal with today's problems. Congress should begin to deal with this problem.

I suggest a Presidential Commission be appointed. Put all the people that you have heard over the last several days of hearings who disagree on this issue in a room and give them a time limit to work something out. It would happen.

Senator COLLINS. I like that idea.

Ms. FOREMAN. We keep doing this minuet. The industry people say they oppose it. We say we support it. Put everybody in a room and say, fix it. I think it would get fixed. And I think what would come out would be a document that would be useful in educating the American people and the Congress about why it is worth going through the struggle to reorganize.

I am going to keep coming back to the resource issue. It would be resolved in small part by reorganizing. There are duplicate administrative and budget staffs at these agencies. Those could be eliminated by bringing the agencies together. You have a few places where you have FDA and FSIS and OSHA inspectors a plant.

Most importantly, you could redeploy resources more easily, because all would work for the same agency. It does not have to be an independent agency. I could think of a lot of ways you might do it.

Let me address equivalency for just a minute. It is a first step. It is probably the easiest of the things that you might do.

USDA's equivalency system works pretty well for what it is. Organoleptic inspection is not a good system for today's problems and equivalency does not work to the extent that it is demanding equivalence on things that are not important any more.

As USDA moves to a HACCP system and to performance standards that limit pathogen levels in a product, you answer much of the fear that the industry has about how to define equivalency. If equivalency means you have to meet the same performance standard that people in the United States meet in terms of microbial contamination of the product, that is a science-based standard for equivalency.

Thank you.

Senator COLLINS. Thank you.

Mr. Hahn, is it more an issue of organization, resources, or do we need a whole new system?

Mr. HAHN. I agree that it is a combination of all three. I think the immediate need is to add additional resources and to take measures to fix the existing system. But I also support the creation of a single food safety agency.

Senator COLLINS. Thank you.

Dr. Levinson, you represent the Public Health Association and, thus, have knowledge of the interaction among the various levels of government on food safety. In one of our hearings we heard from the CDC which described the trace back process and the necessity for a physician to identify a foodborne illness which oftentimes does not occur, and then report it to the appropriate officials.

How well do you think that system works, the coordination among the private physician, the local public health agency, the State and the CDC and Federal officials?

Dr. LEVINSON. Let me begin by stating that even in areas where we have reporting by law, for example, a number of infectious diseases that must be reported, we consider an outstanding result has occurred when 50 percent of the cases are reported.

So, even when required by law it is very, very difficult because it is troublesome in the current system, pencil and paper and so on, to get the reports in, to remember to meet deadlines, etc.

Where you have a totally voluntary system like we have for food safety, it basically does not work at all. There are attempts to improve it with FoodNet and so on and, indeed, what they involve is using other sources. You do not rely on the physician's report, you look at the laboratories, you look at other sources of information and then trace cases from that source rather than waiting for only one group to report.

I think that improves the situation somewhat, but it does not make it perfect. So, I think that this is a work in progress and we still have a long way to go. I would be happy if we had 50 percent of the cases of foodborne illness reported but we are very far from that now. And I think the only way we will get to a level even that high is if we do involve many other components besides just the physicians reporting in order to attempt to detect and trace cases of foodborne illness.

Senator COLLINS. At one of our hearings we had a witness who was a scientist himself and who had been stricken as a result of eating the infamous Guatemalan raspberries. And he diagnosed himself as a result of reading a *New York Times* story about the outbreak. He had been to his physician and his physician thought he just had some sort of intestinal flu. And he ended up diagnosing himself. But he had the advantage of being a trained scientist and having seen the *New York Times* story.

I guess my final question to all of you is how much more education do we need to do to allow consumers to recognize foodborne illnesses as well as improve their own food handling since we know that that is a fairly common cause.

And how much more do we need to do to educate the medical community to recognize foodborne illnesses?

Dr. Kava.

Ms. KAVA. Well, I think we still have a lot to do to educate consumers. I think polls and hidden cameras that try to document how frequently people wash their hands, for example, after using the restrooms, both consumers, ordinary people as well as medical professionals, has revealed an astoundingly low percentage of people who are compliant with this very basic issue of safe, well, just general sanitation and safety. And I think that that needs to be emphasized over and over again.

But some of it may also be out of control of consumers because more and more of us are eating out much more frequently in which case what we need to do is educate food service workers to a greater extent or to the greatest extent possible about sanitation.

I think this needs to be ongoing. Perhaps there could be something done in schools so that children start learning about these types of issues very early on and not just wait until people are adults and they get sick.

The issue is also one of how can you alert people without panicking them, without every stomach ache turning into *E. coli* 0157H7 or something like that? And I think that one needs to teach people how to distinguish between a real foodborne illness or something that could be serious.

FDA has now promulgated rules about unpasteurized juices with warning signs up. I think that is very important and I think that I would like to see some realistic information get out there about the relative risks of things like organic foods which are often fertilized with manure, which is a great carrier for all sorts of bacteria and the necessity for people to be very careful about washing organic foods.

I mean I know people who—and this is an anecdote—who say, well, I don't have to peel my carrots, they are organic. And this is someone who is very concerned about getting organic produce because she does not want to eat pesticides.

So, I think that some of these relative risks need to be put out there so that consumers can really see what is going on. Because I think that we are having sort of an anti-science movement in this country now and that people think that organic is natural, organic is safer, and that they do not have to take precautions.

Senator COLLINS. I think you have raised an excellent point. Just recently the daughter of a friend of mine in Maine got very ill because of *E. coli* as a result of drinking unpasteurized milk. And I am stunned that she would let her daughter drink unpasteurized milk but she thought by going to this local farm she was getting the freshest, best possible milk for her daughter. And her daughter fortunately is all right but was hospitalized for a number of days and it was a serious incident of foodborne illness.

But I, perhaps also as we teach people to eat more fruit and vegetables, we need to teach them to wash the fruit and vegetables before they eat it.

Ms. KAVA. Yes.

Senator COLLINS. But, Dr. Levinson, do you have any comment on the need for more consumer and professional education in this area?

Dr. LEVINSON. Yes. Indeed, I certainly agree that more consumer education is important. First of all, although we do eat out more, people still handle a great deal of raw food in their home and they do misuse that food in terms of food safety because they do not know the rules or they ignore them.

I am very impressed that a lot of packaging of turkeys and other products now show you or remind you what you should do but I think many people ignore that, those admonitions.

But over and above all of that, over and above personal safety and safety of the family, I think that it is important to educate people about food safety so that as consumers and as citizens they can make intelligent decisions about issues such as what we have discussed today.

Unless the public understands the implications of and the requirements of preserving the safety of the food supply, they will not be able to assist their legislators and others in dealing with issues like how do you handle the international food situation, what do you do about inspection of processing plants and so on?

When something dramatic happens, like the *E. coli* outbreaks where people die, then the publications, the newspapers are filled with information and people become very agitated and activated and then a few weeks later they forget about it. I think this is an ongoing issue. We are literally what we eat. And we do need an in-

formed public to lead us all to a higher plateau of understanding and activity.

As far as the medical profession, there is no question that they need further information about this and many other topics. What they will do with this information will vary. Hopefully they will report significant cases of foodborne illness because for those cases there is a necessity to trace the source of the contamination of the food and unless they report meticulously about these cases, this tracing will never occur and we will continue to live with estimates of 3 to 81 million cases of foodborne illness a year. We will never be able to close the difference and those statistics are not meaningful.

But also they need to be aware that many increasingly foodborne illnesses are due to emerging infections and the first evidence we have of the emergence of these infections may, indeed, be foodborne illnesses. And the infections, themselves, as with *Cyclospora,* may not involve a lot of people, but they raise a number of troubling issues about how well we are monitoring the food supply and how difficult it is to detect something like *Cyclospora* in incoming food.

They also raise issues about strawberries versus raspberries. You do not wash raspberries because they fall apart. So, a restaurateur would use them, fresh from the box without worrying about their sanitary condition.

So, I think that education of everybody is very essential and has to be targeted, it has to be persistent and it has to be very effectively presented.

Senator COLLINS. Ms. Foreman, in responding to this question, could you also comment on what you see as the government's role in encouraging more education in this area?

Ms. FOREMAN. Yes. Thank you.

I want to subscribe to what Dr. Levinson said about this also being a process of educating the public about how public policy affects their health. I believe everybody has to practice self defense. In the end, we defend ourselves.

I am really very pleased that Public Voice for Food and Health Policy and I are both involved with the Partnership for Food Safety Education that is a combination of industry, consumers and government. It put out the Fight BAC materials and is working hard to get those distributed as widely as possible.

We need education but we also have to have education that competes in a market place of very slick messages. Food safety messages have to compete with the swoosh and that is hard. It is not the sort of thing that government educators or even public health educators are used to doing.

We need messages that compete. The Fight BAC logo and the icons around it provide a fast, quick indication of what you need to do. It should refresh information that you have gotten elsewhere.

I would like to see those messages to wash your hands, keep your food separate, do not cross contaminate, keep food cold, cook food well, become ubiquitous. I would like to see them printed on every grocery bag that leaves a supermarket and on carry-out food from all the chain restaurants.

We are just beginning to scratch the surface of what can be done with this. There is agreement on those four messages. The more

people who come in with that message in slightly varied form the better off it is for all of us.

Government has an important role to play in advancing that information. And government has been working very hard at it. I have not thought about what government might do beyond that. There have been suggestions that the government urge people to accept irradiation of food and to educate the population as the government educated us at one time about the importance of pasteurization.

I have some reservations about government promoting a particular process. But I do think that we need government to play a role where there is clearly no disagreement about what needs to be said.

Senator COLLINS. Thank you.

Mr. Hahn.

Mr. HAHN. I agree that we need to educate medical professionals, retail food service and also consumers. I think that the schools are a good place to educate consumers if they are willing to take on that task and have the kids teach their parents. Another suggestion that has been made is to have the Federal Government issue food safety guidelines like the Dietary Guidelines for Nutrition, and I think that would be a good idea to have a single source of food safety information rather than getting the information out in dribs and drabs.

Senator COLLINS. Thank you.

I want to thank all of the panel for your testimony today. We do look forward to continuing to work with you. I rather like Ms. Foreman's idea of bringing all the interested parties together and locking them into what would have to be a very large room, I believe, perhaps denying them water and food until an agreement is reached.

But in all seriousness, our intention is to work with everyone who is interested on this issue to try to come up with legislation that would really make a difference in the safety of the food we eat with particular emphasis on food imported from other nations because that has been the primary focus of our investigation.

Again, I thank you very much for your contributions today and the contributions of the previous panel as well. The hearing record will remain open for 10 additional days.

I want to take this opportunity to thank my staff which has worked extremely hard on this investigation. In particular, we have benefitted from the expertise of a food scientist, Stephanie Smith, who has been working with us during the past year. She has been invaluable in bringing to us an understanding of what risk-based analysis means and bringing us some scientific expertise to this investigation.

So, I am grateful for the help of Stephanie and, indeed, of all my staff in this area.

Thank you very much and this hearing is adjourned.

[Whereupon, at 11:53 a.m., the Subcommittee adjourned.]

APPENDIX

United States General Accounting Office

GAO

Testimony

Before the Permanent Subcommittee on Investigations,
Committee on Governmental Affairs,
U.S. Senate

For Release on Delivery
Expected at
9:30 a.m. EDT
Thursday
September 10, 1998

FOOD SAFETY

Weak and Inconsistently Applied Controls Allow Unsafe Imported Food to Enter U.S. Commerce

Statement of Lawrence J. Dyckman,
Director, Food and Agriculture Issues,
Resources, Community, and Economic
Development Division

GAO/T-RCED-98-271

Madam Chairman and Members of the Subcommittee:

We are pleased to be here today to testify on federal agencies' efforts to prevent unsafe imported foods from entering the U.S. market. With the number of imported food shipments increasing–more than doubling over the past 6 years–ensuring the safety of these imported foods becomes more challenging. As we reported to you in May,[1] we found weaknesses in federal agencies' controls over shipments of imported foods that allow unsafe foods to enter domestic commerce. The agencies responsible for monitoring imported food shipments are the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which is responsible for meat, poultry, and some egg products; the Food and Drug Administration (FDA), which is responsible for all other food products; and the U.S. Customs Service (Customs), which refers imported food to FSIS and FDA for their review before releasing the shipment into U.S. commerce.

When a shipment arrives at a port of entry, Customs notifies FSIS or FDA, which determine whether the shipment should be held for inspection or be allowed to enter the U.S. market. FDA-regulated shipments are held by importers at their own warehouses. All FSIS-regulated shipments are held at an FSIS-approved import inspection station. While specific procedures vary by port, if a shipment is refused entry because it does not meet U.S. standards for food safety, FSIS or FDA, in conjunction with Customs, require that the importer properly dispose of the shipment by reexporting or destroying it. Customs is then responsible for ensuring the destruction or reexport of the refused shipment. Customs may penalize importers for (1) not presenting a shipment for inspection when ordered to do so by FDA or FSIS, (2) not redelivering an FDA- or FSIS-

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[1]Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, Apr. 30, 1998) and Food Safety: Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable (GAO/T-RCED-98-191, May 14, 1998).

refused shipment to Customs for proper disposal in a timely fashion, or (3) not delivering it at all.[2]

In response to our earlier work, you asked us to obtain additional information on the extent to which federal controls ensure that food importers present shipments for inspection when required and that shipments refused entry are destroyed or reexported. You also asked us to identify ways to strengthen these controls. To assess the extent and effectiveness of federal controls over imported foods, we reviewed FDA and FSIS import activities and files on selected imported shipments at various ports to determine the ultimate disposition of the shipments.[3] At each FDA port reviewed, we examined the records of FDA import shipments chosen randomly from a list of refused entries and selected entries that were not made available for FDA inspection during the 6-month period from September 1997 through February 1998. At each FSIS port reviewed, we examined selected records on refused entries in calendar year 1997. In addition, we interviewed Customs, FDA, and/or FSIS officials at various ports. We also spoke with representatives of customs brokers and importer associations to discuss opportunities to strengthen controls. In order to ensure the accuracy of the information in this testimony, we met with officials of FDA, FSIS, and Customs, who generally agreed with the facts presented. We performed our work in accordance with generally accepted government auditing standards from May to September 1998.

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[2]In this testimony, the term penalty refers to Customs' actions to collect "liquidated damages" under a bond posted by an importer to ensure it properly presents shipments for inspection or disposes of shipments that have been refused entry.

[3]We reviewed the records of selected FDA shipments at Los Angeles and San Francisco, California; Seattle and Blaine, Washington; Laredo and Pharr, Texas; Miami, Florida; and New York, New York. We reviewed the records of selected FSIS shipments at Los Angeles and San Francisco, California; Seattle, Washington; Houston, Texas; Miami, Florida; and Newark, New Jersey.

In summary, FDA's current controls provide little assurance that shipments targeted for inspection are actually inspected or that shipments found to violate U.S. safety standards are destroyed or reexported. Because importers, rather than FDA, retain custody over shipments throughout the import process, some importers have been able to provide substitutes for products targeted for inspection or products that have been refused entry and must be reexported or destroyed, according to Customs and FDA officials. Moreover, Customs and FDA do not effectively coordinate their efforts to ensure that importers are notified that their refused shipments must be reexported or destroyed. Finally, Customs' penalties for violating inspection and disposal requirements may provide little incentive for compliance because they are too low in comparison with the value of the imported products or they are not imposed at all. As a result of these weaknesses, shipments that failed to meet U.S. safety standards were distributed in domestic commerce. Because FSIS requires unique identification marks on, and maintains custody of, each shipment of imported foods under its jurisdiction, we did not find similar weaknesses in FSIS' controls over the shipments we reviewed, although we did identify some coordination problems between FSIS and Customs.

Federal controls would be strengthened by consistently implementing current procedures and by adopting new procedures. Customs and FDA officials and representatives of importer and broker associations identified a number of ways to improve agencies' controls over incoming shipments, strengthen interagency coordination, and provide stronger deterrents against repeat violators. Each of these approaches has advantages and disadvantages that should be considered before making any changes.

BACKGROUND

FDA and FSIS must approve the release of the products they regulate before importers can distribute them in the domestic market. These agencies inspect products to ensure that they comply with U.S. food safety requirements. FDA electronically screened all 2.7 million entries of imported foods under its jurisdiction in fiscal year 1997 and physically

inspected about 1.7 percent, or 46,000, of them. FSIS visually inspected all 118,000 entries of imported meat and poultry under its jurisdiction in calendar year 1997 and conducted physical examinations on about 20 percent of them.

Importers must post bonds with Customs to allow them to move the shipment from the port. The bond amount is intended to cover any duties, taxes, and penalties. Importers generally obtain continuous bonds that provide coverage for multiple shipments over a specified time period. The amount of a continuous bond is based primarily on a percentage of duties paid in the previous year. Importers can also purchase bonds for single shipments (single-entry bonds) in an amount 3 times the declared value of the shipment.[4] Once Customs reviews entry documents and verifies the bond, it conditionally releases the shipment to the importer.

After the conditional release, FSIS and FDA exercise different controls over the shipment, according to their statutory and regulatory authorities. FSIS generally requires the importers of the products it regulates to deliver them to approved import inspection facilities for storage until the products are released or refused entry. If FSIS refuses entry, it notifies the importer, who must arrange for reexport, destruction, or conversion to animal food within 45 days. The shipment is not released from FSIS' custody until the importer presents documents to FSIS showing that arrangements have been made.

In contrast, under the Federal Food, Drug, and Cosmetics Act, as amended (FFDCA), importers are allowed to retain custody of food imports subject to FDA regulation in their own warehouses throughout the entire import process, from pick-up at the port of entry to release, destruction, or reexport. FDA releases most shipments without inspection. If FDA decides to examine a shipment, it asks the importer to make the shipment available for inspection at a place of the importer's choosing. If FDA refuses to allow the shipment to enter the United States as a result of this inspection, it notifies Customs and the

[4]The declared valued is based on the cost of the goods to the importer.

importer and gives the importer 90 days to reexport or destroy the refused shipment. FDA's decision to refuse entry may occur immediately after inspection or may occur several days or weeks after a sample is collected, when laboratory results become available.

If a shipment is not presented for inspection as requested by FDA or FSIS or is refused entry by FDA or FSIS, Customs is to notify the importer through a redelivery notice to (1) make the shipment available for FDA or FSIS inspection or (2) redeliver the refused shipment for Customs' supervised reexport or destruction. Customs can penalize an importer that fails to (1) make a shipment available for inspection, (2) destroy or reexport a refused shipment within the time frame set out in the Customs redelivery notice, or (3) dispose of the shipment under Customs' supervision. Customs initially assesses penalties at the maximum amount allowed–3 times the value of the shipment declared on the Customs entry form, up to the amount of available bond coverage. According to Customs' guidelines, Customs must follow FDA's penalty recommendation when an importer fails to redeliver a refused shipment for export or destruction. Customs may reduce the penalty when the shipment is returned (1) late but disposed of under Customs' supervision or (2) on time but not disposed of under Customs' supervision. According to Customs officials, they cannot impose penalties if Customs does not issue a redelivery notice to the importer within 120 days of the FDA refusal date.

IMPORTERS CAN CIRCUMVENT FDA AND CUSTOMS INSPECTION AND DISPOSAL REQUIREMENTS

Weak and inconsistently applied controls have allowed some FDA-regulated imported foods that violate U.S. food safety requirements to enter domestic commerce. This occurs when either (1) importers circumvent required inspections or fail to properly dispose of shipments refused entry or (2) federal agencies do not work together to ensure that these shipments are disposed of properly. Although importers are subject to penalties for circumventing inspection and disposal orders, we found such penalties may

not effectively deter violations because the penalties are too low and at times are not imposed at all and therefore fail to serve as a deterrent.

Importers' Custody Over Products Allows
Unsafe Products to Enter Domestic Commerce

Unscrupulous importers bypass FDA inspections of imported food shipments or circumvent requirements for reexporting or destroying food shipments that were refused entry, according to Customs and FDA officials at the ports we visited. This occurs, in large part, because, under FFDCA, importers are allowed to maintain custody of their shipments throughout the import process. Additionally, (1) FDA does not require shipments to have unique identifying marks that would aid in ensuring that other products are not substituted for those targeted for inspection or disposal and (2) importers, under FFDCA, are allowed a long period of time to redeliver refused shipments to Customs for disposal, which facilitates substitution by unscrupulous importers.

Recognizing this problem, Customs has conducted and is still conducting operations at a number of ports to detect importers that attempt to circumvent inspection and disposal requirements. For example, in a San Francisco operation that started in October 1996 and was known as "Shark Fin," Customs and FDA found that importers had diverted trucks en route to inspection stations so that suspect products could be substituted with acceptable products. According to Customs investigators, the operation revealed that six importers were sharing the same acceptable product when they had to present a shipment for inspection–a practice known as "banking." In a follow-up operation in San Francisco, known as "Operation Bad Apple" and started in July 1997, Customs and FDA found a number of substitution and other problems, such as invoices that falsely identified the product. Customs' concerns were further validated when this second operation found that 40 of the 131 importers investigated had import shipments with discrepancies, such as product substitution and false product identification. According to a Customs official,

10 of the importers were previously identified as suspicious, while the other 30 importers had been considered reliable until the investigation.

Identifying the substitution of products prior to inspection is difficult and labor-intensive, according to FDA and Customs port officials. Because FDA-regulated imports do not have unique identification marks that associate a shipment with the import entry documents filed with Customs, extra efforts are required to identify substitution, such as marking or documenting the products at the port before they are released to the importer, then checking the products when they are presented for inspection. FDA and Customs officials believed that placing additional staff at the ports for such efforts, as in the San Francisco operations, could not be sustained as a normal practice, given the resources required and other priorities.

Substitution problems have also occurred after inspections, when importers are ordered to redeliver refused shipments to the port for destruction or reexport. Three of the eight ports we reviewed routinely examined FDA-regulated shipments delivered for reexport or destruction to detect substitution, according to Customs and FDA officials. At two of these ports--New York and Blaine--Customs found that substitution had occurred on outbound shipments. For example, in New York, Customs instituted a procedure in 1997 to physically examine selected food shipments that were refused entry and were scheduled for reexport. Officials began this procedure after periodic examinations found that some importers had substituted garbage for the refused shipments that were being reexported. For the 9-month period of October 1, 1997, through June 30, 1998, Customs found discrepancies in 31 of the 105 FDA-refused shipments it examined. Nine of the discrepancies were for product substitution and 22 were for shortages--only part or none of the refused shipment was in the redelivered containers. For example, in one instance, the importer presented hoisin sauce for reexport that had a later production date than the date of the entry into the United States on the original refused shipment. Customs officials believed that the importer distributed the original refused shipment into domestic commerce and substituted the hoisin sauce to avoid detection and penalty.

At the other five ports, Customs does not systematically examine the shipments delivered for disposal to detect substitution or only examines them for destruction. For example, at Laredo, Customs officials said they only review the documents provided by the importer and do not examine the shipment to verify that the products being reexported or destroyed are the same products that were refused entry. At Miami, Seattle, and Los Angeles, Customs or FDA officials may examine some products presented for destruction, but, as at the Laredo port, only review the documents provided by the importer to verify the export of refused shipments. At San Francisco, a Customs official told us that he reviews the paperwork on the refused shipment and the paperwork on the shipment presented for destruction or reexport. None of the five ports routinely physically examined the export shipments to ensure they contained the products that were refused entry and listed on the export documents. Customs officials told us they do not have enough time for inspectors to verify each shipment presented for destruction or reexport, given the number of refused shipments and other priorities.

A number of factors contribute to FDA's and Customs' problems in ensuring that targeted shipments are actually inspected and that refused entries are properly disposed of. First, under FFDCA, importers are allowed to maintain custody of their shipments throughout the import process, thus providing importers with the opportunity to circumvent controls.

Second, imported food shipments under FDA's jurisdiction are not required to contain unique identification marks. As a result, it is difficult to verify whether the FDA-regulated shipments presented for inspection were the actual shipments being imported or whether refused shipments were destroyed or reexported. Furthermore, when FDA determines that a shipment is unsafe, FDA does not mark the shipment to show it was refused entry. In contrast, FSIS requires that imported food shipments under its jurisdiction contain unique identifying marks and are retained under its custody until disposal, and when it refuses entry, it stamps each carton "U.S. Refused Entry." Without such markings, Customs and FDA have less assurance that an importer will not substitute products either before inspection or, in the case of refusal, before redelivery for export or destruction.

Furthermore, there is no assurance that an importer will not reimport a refused shipment at a later date.

Third, under FFDCA, importers of FDA-regulated products are given 90 days to redeliver refused shipments for proper disposal, which is twice the amount of time that FSIS regulations give importers of FSIS-refused shipments. According to Customs and FDA officials, allowing an importer up to 90 days to dispose of refused products while retaining custody of the shipment provides more time for the importer to arrange for substitution. That is, unscrupulous importers will distribute into domestic commerce shipments refused entry and substitute for reexport a shipment that arrives at a later date.

Customs and FDA Often Do Not Coordinate Efforts to Prevent Unacceptable Products From Entering U.S. Market

At five of the eight ports we examined, Customs and FDA do not effectively coordinate their efforts to ensure that importers are ordered to redeliver refused shipments for disposal. At two of these ports--Los Angeles and New York--Customs was unaware of FDA's refusal notices for 61 to 68 percent of the shipments we reviewed. At the other three--Laredo, Pharr, and Seattle--the lack of coordination appears to be less problematic. Nonetheless, as a result of these coordination problems at the five ports, Customs had not issued notices of redelivery to the importers. In contrast, at Miami, San Francisco, and Blaine, Customs and FDA officials coordinate their efforts to issue refusal notices and redelivery notices through joint agency teams or regular reconciliation of records. (See app. I for information we collected on each port's FDA-refused shipments.)

Refused shipments that are not properly disposed of are likely to have entered domestic commerce. For example, according to a New York Customs official, over three-quarters of the cases we reviewed in which Customs did not have an FDA refusal notice--48 out of 63--were presumably released into commerce because Customs did not issue a notice to

the importer to redeliver the shipment. In Los Angeles, we found that Customs had not issued a redelivery notice and had no records of disposal for 21 out of 54 shipments we reviewed.[5] Some of these refused shipments that may have been released into commerce posed serious health risks: 11 of the 48 New York cases and 8 of the 21 Los Angeles cases were refused by FDA because they contained salmonella, a bacteria that can cause serious illness.

It is unclear why Customs was not aware of all the imported food shipments refused entry by FDA. While FDA officials told us they either mailed or hand-delivered notices of refusal to Customs, Customs officials said they did not receive them. Nonetheless, Customs should have been aware of a coordination problem because importers sometimes returned shipments for disposal after receiving a refusal notice from FDA but without having received a Customs redelivery notice. For example, at New York, we found indications that importers returned shipments for destruction or reexport in 15 of the 63 cases in which Customs did not issue a redelivery notice.

At Miami, San Francisco, and Blaine, Customs and FDA officials work together to ensure that required redelivery notices are issued on FDA-refused entries. In Miami, a joint Customs-FDA team sends out a single notice to the importer stating that the shipment has been refused entry and that the importer must return it for proper disposal within 90 days. In San Francisco and Blaine, the agencies reconcile their refusal and redelivery notice records each week. As a result of their efforts, we found that Customs was aware of FDA's refusal notices at these three ports in about 95 percent of the cases we reviewed.

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[5]When we brought this problem to Customs' attention at Los Angeles and New York and asked what action could be taken on these cases, the officials said they would not issue redelivery notices for any of the shipments with refusals older than 120 days because Customs cannot impose liquidated damage penalties for violations after that time.

Although we found that Customs was frequently not aware of FSIS-refused shipments, we did not find comparable problems of imported food products being distributed domestically after they had been refused entry. According to FSIS officials, when FSIS rejects a shipment, it only notifies the importer of the refusal. The importer, in turn, must notify Customs of the refusal and obtain Customs' authorization to destroy or export the shipment, but this information often does not reach Customs' files. In Seattle, for example, of the 15 FSIS cases we reviewed, Customs could not locate files for 7 cases, and only 3 of the remaining 8 case files at Customs contained records of FSIS refusals or Customs notices of redelivery. Despite this apparent lack of coordination, we found records at the FSIS import inspection facility that indicated the refused shipments were disposed of properly. We believe that FSIS' controls over import shipments–requiring unique markings on each carton, retaining custody of shipments until they are approved for release or properly disposed of, and stamping "U.S. Refused Entry" on rejected shipments–reduced opportunities to bypass import controls.

Current Penalties Are Not Effective Deterrents

Customs' penalties for failure to redeliver refused shipments do not effectively deter violations because they are either too low compared with the value of the product or not imposed at all, according to Customs and FDA officials at the ports we reviewed.[6] According to these officials, importers often view these penalties as part of the cost of doing business. Some officials believe importers consider the amount of the penalty from one violation will be covered by the gains made from other shipments that manage to enter commerce.

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[6]Even though these deterrents may not be effective, FDA and Customs have other general authority to prevent the entry into the country or distribution into commerce of adulterated products. This authority includes the seizure of products, prohibitions on distribution, and other actions. See, for example, 21 U.S.C. sections 332, 333, and 334; and 19 U.S.C. section 1595a(b). However, according to FDA and Customs officials, these actions are taken in egregious cases.

Although violations for failure to redeliver shipments for which Customs issued a redelivery notice are initially assessed at 3 times the declared value of the shipment, an importer could still profit from the sale of a refused shipment even after buying the product and paying a full penalty for failure to redeliver. For example, we found that the wholesale market price for a 10-pound carton of Guatemalan snow peas ranged from $13 to $15, while the declared value of a 10-pound carton in one refused shipment was $0.75 per carton and the assessed penalty was $2.25 per carton. Thus, in this case, the wholesale value was four to five times the maximum penalty.

In some cases, Customs did not impose the maximum allowable penalty–3 times the shipment's declared value–because the penalty exceeded the value of the bond that the importer had posted.[7] At least 16 of the 162 penalty cases identified by Customs in Miami and 7 of the 50 cases we reviewed in New York had lower penalties imposed because of insufficient bond coverage. In Miami, for example, the importer of a shipment of swordfish that was refused entry for excessive levels of mercury but not redelivered as required could have been assessed a penalty in excess of $110,000, but the importer was actually assessed a penalty of only $50,000–the value of the bond. Customs and FDA officials said the bond amount may not cover the maximum penalty because most importers obtain continuous bonds, whose value is set as a percentage of duties paid in the prior year and is not tied to the declared value of the entries in the current year. According to Customs officials in Miami and New York, if the importer has a history of violations, Customs may require the importer to post single-entry bonds for additional entries.

At three ports–Los Angeles, San Francisco, and Seattle–Customs did not assess as severe a penalty as agency guidelines suggested because officials at these ports were unable to identify repeat offenders and penalize them accordingly. For example, port officials in

[7]The maximum penalty that can be imposed is either three times a shipment's declared value or the value of the importer's posted bond, whichever is the lowest amount.

Seattle said the computer system that records violation information is difficult to access for identifying repeat offenders, given other priorities. Prior to April 1998, Custom officials for the Laredo and Pharr ports said they could not identify repeat offenders for the same reasons. However, New York, Miami, and Blaine maintained their own records on violations and repeat offenders and usually followed Customs guidelines when assessing penalties on repeat offenders in the cases we reviewed.

Finally, Customs officials said they cannot impose penalties in many cases we reviewed because the agency did not issue a redelivery notice to the importer within 120 days of the FDA refusal date. For example, in Los Angeles, we found that 11 cases had refusal notices over 120 days but did not have redelivery notices. Although some importers reexport or destroy their shipments after receiving only the FDA refusal notice, importers that do not redeliver the refused product will not incur a penalty. From their experience, Customs officials believe that in such cases importers distribute the product.

OPPORTUNITIES ARE AVAILABLE TO IMPROVE CONTROLS OVER IMPORTED FOODS

Customs and FDA officials and importer association representatives suggested ways to strengthen controls over imported foods as they move through Customs' and FDA's import procedures. Some of the more promising suggestions are discussed below. Each of these suggested approaches has advantages and disadvantages, costs, or limitations that would have to be considered before any changes are made.

FDA Could Request Customs to Maintain Control of Certain Shipments Until They Are Released

For certain importers that FDA believes are more likely than others to violate import controls because they have a history of violations,[8] Customs and FDA could work together to ensure that substitution does not occur before either inspection or disposal. For example, FDA could target importers, and Customs could order that these importers' shipments be delivered by bonded truckers to an independent, Customs-approved, bonded warehouse pending inspection. Although FDA can request Customs to require importers to present shipments for inspection at a bonded warehouse, it does not routinely use this authority and make such requests. In Los Angeles, for example, FDA officials said they have had Customs make an importer present a shipment to a bonded warehouse only once in the past 2 years. Given their concerns about importers circumventing federal controls over imported foods, Customs and FDA officials at San Francisco and Miami are considering implementing variations on this option. For example, in Miami, Customs and FDA officials are developing a program to require importers of FDA-refused shipments to deliver them into the custody of a centralized examination station, a type of bonded warehouse, for disposal, rather than allowing the importer to retain custody.

This approach has the advantage of preventing the targeted importers from bypassing inspection controls and of ensuring the proper disposal of the targeted importers' shipments that were refused entry. Furthermore, this approach would serve as a deterrent to importers likely to violate requirements because they would have to pay the additional costs associated with unloading a shipment and storing it at a bonded warehouse.[9] Moreover, this approach would not require any change in Customs' authority. Customs currently uses bonded warehouses for its own inspections and could, at FDA's request, require targeted importers to use bonded warehouses.

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[8]FDA is developing through its automated import screening system the capability to identify importers that have a history of food safety-related violations.

[9]Estimates for unloading a 40-foot container range from $350 to $1,000, and storage costs range from $75 to $700 per week, depending on the location.

This approach also has several limitations. First, it does not cover all importers. While ideally it would be preferable to monitor all importers, it may not be practicable because the costs to law-abiding importers would also increase. Second, even if Customs and FDA focused only on problem importers, the agencies would need to develop a coordinated system to identify them. Similarly, this approach would depend on effective coordination after such identification--FDA would need to request Customs to maintain control of a shipment, and Customs would have to act accordingly. As we have noted, effective coordination between FDA and Customs does not always occur.

Targeted Shipments Could Be Marked in Order to Trace Them Throughout the Import Process

Customs and FDA could take steps to better ensure that importers with a history of violations are not substituting products before inspection and are not returning the actual refused cargo for destruction or reexport by adopting variations on controls used by FSIS for meat and poultry imports. To help prevent substitution before inspection, FDA could require the shipments of importers or products with a history of violations to have unique identification marks on each product container and on entry documents filed with Customs. To help ensure that shipments refused entry are destroyed or reexported, FDA could stamp "refused entry" on each carton/container in shipments that it finds do not meet U.S. food safety requirements.[10]

Requiring certain targeted shipments to have unique identification marks would have the advantage of enabling FDA inspectors to better verify that the products presented for inspection were the same products identified on Customs entry documents and help Customs inspectors verify that shipments refused entry were disposed of properly.

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[10]FDA does not have explicit statutory authority to require unique identification marks on each product container or on entry documents filed with Customs nor to stamp "refused entry" on each carton/container. We are unaware of any FDA formal determinations that it would have implicit authority for these actions under its statutory authorities.

Similarly, stamping refused entries would increase the likelihood that they were actually destroyed or reexported and reduce the likelihood that reexported products would reenter the country at a later time.

However, these procedures might be difficult to implement. Requiring unique identification marks on imports (1) would require FDA to develop and implement a marking and labeling system for the wide variety of imported food products from many different countries that it regulates and (2) might negatively affect trade. Furthermore, a requirement to stamp refused entries would be labor-intensive for FDA because FDA, unlike FSIS, does not always have custody of the shipments at the time of refusal and would have to travel to the storage location to stamp the cartons.

Customs and FDA Could Work Together
to Ensure That Importers Are Issued Redelivery Notices

Customs and FDA could develop a method of ensuring that importers whose shipments are refused entry into the United States are issued notices to redeliver their cargo. Two approaches were suggested to us. First, Customs could retrieve information from its own database on FDA's refusals. Customs records all import shipments in its Automated Commercial System (ACS), and FDA communicates its refusal notice to the importer through ACS. Currently, however, Customs' system is not programmed to identify FDA refusals.

Second, in lieu of the first approach, or until this approach is implemented, Customs and FDA could work out a manual system, such as reconciling FDA refusal and Customs redelivery notices.

Either of these approaches has the obvious advantage of ensuring that Customs is promptly aware of all FDA refusals so that it can issue redelivery notices. The database approach, however, would require some reprogramming of ACS to enable Customs to

access FDA's refusals as well as training of Customs officials to ensure that they know how to use the software. The second approach would also address the coordination problem but would require more staff time.

The Congress Could Reduce the 90-Day Period Importers of FDA-Regulated Foods Are Allowed for Redelivery

The Congress could reduce the time allowed for redelivery of FDA-regulated shipments to require importers to dispose of refused shipments more quickly and more in line with the other agencies. By statute, importers of FDA-regulated foods are allowed 90 days to redeliver products after being issued the notice of refusal, in contrast to importers of FSIS-regulated foods, which are allowed a 45-day redelivery period. FDA officials at two ports said the longer time period is intended to give importers enough time to arrange export shipping of refused shipments. In New York, however, Customs officials said some importers use the longer time period to obtain products to substitute for the refused shipments.

The advantage of this approach would be to reduce the opportunity for importers to distribute the products into domestic commerce or to prepare substitute products for disposal. However, importers would have less time to consolidate refused entries with other exports, which may increase their shipping costs. Reducing the redelivery period would also require changes in FDA's statutory authority.

Penalties Could Be Strengthened to Serve as a More Effective Deterrent for Repeat Violators

Under Customs' current practices, penalties can be lower than the wholesale market value of a shipment and therefore not effectively prevent refused imported foods from entering domestic commerce. To create a more effective deterrent, Customs could take one or more of the following suggested actions.

First, Customs could increase the continuous bond requirement for importers with a history of violations so that the bond would cover potentially higher penalties. Rather than base the calculation for continuous bonds primarily on duties paid in the previous year, Customs could adjust the formula to include the history of violations and damages assessed during the earlier period. Second, Customs could require importers with a history of violations to post separate, single-entry bonds for each import shipment. The single-entry bond amount is 3 times the declared value of the shipment. Finally, Customs could impose higher penalties on repeat violators, as allowed by its own guidelines, by providing the means for Customs staff to identify importers with a history of violations. Currently, Customs cannot always identify repeat offenders.

These approaches have the advantage of creating a more significant monetary disincentive to importers considering circumventing federal controls. The first two approaches would impose higher costs on repeat violators because they involve added expenses in increasing the level of a continuous bond or purchasing individual bonds for each shipment. The final approach would enable Customs to follow its own guidelines when assessing penalties on repeat violators.

The first two approaches, however, would require additional work by Customs staff at each port to review and set bond requirements. The last approach would require Customs to correct deficiencies in its penalty database to allow Customs staff to identify repeat violators.

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This concludes my prepared testimony. I would be happy to respond to any questions that you and Members of the Subcommittee may have.

GAO'S ANALYSIS OF FOOD SHIPMENTS ENTERING THE UNITED STATES FROM SEPTEMBER 1997 THROUGH FEBRUARY 1998 THAT WERE REFUSED ENTRY BY THE FOOD AND DRUG ADMINISTRATION

Port of entry	Total entries refused[a]	Refused Entries GAO reviewed	Refused entries for which Customs had no information and did not issue a redelivery notice		
			Total entries	Entries redelivered	Entries not redelivered
Blaine, WA	40	25	1	1	0
Laredo, TX	147	50	2	0	2
Los Angeles, CA	315	88	54	33	21
Miami, FL	228	91	2	1	1
New York, NY	326	93	63	15	48
Pharr, TX	100	36	5	5	0
San Francisco, CA	205	71	6	0	6
Seattle, WA	64	33	6	3	3
Total	**1,425**	**487**	**139**	**58**	**81**

[a]Customs refers to an entire shipment as an "entry," while FDA breaks down the contents of a shipment into "entry lines." As used in this table, "entries" refers to FDA's entry lines.

(150654)

STATEMENT OF RICHARD J. HOGLUND
DEPUTY ASSISTANT COMMISSIONER
OFFICE OF INVESTIGATIONS
UNITED STATES CUSTOMS SERVICE
BEFORE THE SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
SEPTEMBER 10, 1998

Good morning Madam Chairwoman and Members of the Subcommittee. My name is Richard Hoglund. I am the Deputy Assistant Commissioner, United States Customs Service, Office of Investigations. It is a pleasure to be here today to discuss some of Customs investigative efforts in recent years focusing on illegal imports of tainted foodstuffs. I am well aware of the Subcommittee's oversight work in this area including the hearings held earlier this year. While my statement primarily highlights some recent cases and the schemes uncovered, I thought it would be helpful to give a brief overview of Customs mission responsibilities and challenges we face.

The United States Customs Service enforces more than 400 laws for more than 40 U.S. agencies, including the Food and Drug Administration (FDA) and the U.S. Department of Agriculture. In many cases, Customs limited statutory or regulatory authority to take independent action against imported products. Instead, Customs derives its authority to prohibit the importation, exportation, or seizure of merchandise from the direction and orders of the regulating agencies. Indeed, the work Customs performs for the FDA is very much like our work with the Departments of State, Commerce, and Energy in the enforcement of U.S. export laws governing weapons, technology, and nuclear material exports.

Customs multi-faceted mission is one of the most diverse of any law enforcement agency in the United States. In addition to serving as the Nation's primary border interdiction agency, Customs is charged with combating child pornography, narcotics smuggling, money laundering, arms trafficking, stolen automobile exports, cargo theft, revenue fraud, intellectual property rights violations, trafficking in endangered species, importations of goods made with forced or indentured child labor and the importation of tainted foodstuffs. Furthermore, Customs processes more than 1.2 million people and 27 thousand trucks and containers crossing through our borders daily.

While Customs foremost priority continues to be narcotics interdiction, protecting the public health and safety of our Nation is indeed a priority of our agency's Trade Enforcement Strategy. Preventing the importation of tainted foodstuffs presents a unique challenge. Unlike the concealment of illegal narcotics in false compartments or within otherwise legitimate merchandise, tainted foodstuffs can come into the country in plain sight.

Since 1993, Customs has conducted more than 134 investigations relative to the importation of tainted foodstuffs. Before I address a few of these cases, I would like to take this opportunity to note that these cases are a result of the cooperative relationship between FDA's investigative offices and Customs.

OPERATION SHARK FIN

In April 1996, the Special Agent in Charge, San Francisco office developed information regarding the illegal importation and smuggling of adulterated foodstuffs and the bribing of public officials. Subsequently, in November 1996, a joint undercover investigation was initiated with the Food and Drug Administration, Office of Criminal Investigations and the Department of Health and Human Services, Office of the Inspector General. This 10-month investigation disclosed that a licensed Customhouse Broker and two FDA Consumer Safety Inspectors had facilitated a scheme to allow adulterated foodstuffs, including real and imitation shark fins, abalone, bird nests, dried oysters and scallops to illegally enter the commerce of the United States from Asia.

In September 1997 the undercover operation concluded with the arrests and indictments of the broker and the two FDA inspectors, along with 11 other individuals and one company. One individual who was indicted is currently a fugitive. Five containers of adulterated foodstuffs valued at approximately $300,000 were seized. The targets of the investigation had inaccurately described the contents of two containers and attempted to bribe FDA inspectors on the contents of the other three containers. This was done to avoid the inspection and laboratory testing by the FDA of the imported foodstuffs.

This is how it worked: In December 1996, Customs opened an undercover brokerage/storefront business utilizing the Customhouse broker as a full time employee. The storefront was used to monitor and record illegal transactions between the broker and the targeted individuals. The operation focused on individuals with whom the broker had conducted illegal transactions in the past.

In the course of the operation more than 100 undercover contacts with various targets were made. During the undercover negotiations several targets expressed interest in offering monetary bribes to an FDA employee in exchange for utilizing his/her position to sign FDA entry notices containing fraudulent information. This action would allow for the release of the FDA regulated food shipments without examinations by the FDA. An undercover agent posing as an FDA inspector was introduced to the targets. The targets ultimately offered to bribe the undercover agent in an attempt to circumvent Customs and FDA examinations.

Prior to Operation Shark Fin, the broker had assisted in activity using various schemes to get illegal merchandise into the country. The intent of those schemes was to circumvent inspection by Customs and FDA. In one scheme, the importer would switch contaminated merchandise with "clean" merchandise when an inspection was required. The switch would occur between

the time the cargo was moved from the port where the vessel was docked to the location of the warehouse for the inspection. If samples for laboratory analysis were to be taken at the importer's premises, the importer would have a small quantity of a "clean" product available to submit for testing.

When merchandise is appropriately inspected, tested and found to be contaminated, an importer has the option of re-exporting the merchandise from the United States or destroying the merchandise. In some instances, if the importer elected to re-export the merchandise, the same merchandise would be imported back into the United States at a later date. In the event that the importer elected to destroy the merchandise, substituted merchandise would sometimes be destroyed instead of the required merchandise. The importer would usually destroy "trash" similar in weight to the merchandise they were supposed to destroy.

In order for the importer to attempt to avoid penalty action on the importation of unmanifested and/or smuggled merchandise, the importer would use a "Big Mistake" letter. The "Big Mistake" letter would offer various excuses such as the wrong merchandise had been sent by the supplier, the shipment was sent to the wrong country and was not supposed to be shipped to the United States, a mix-up had occurred when the container was loaded, or that the importer had fired or disciplined the employee that made the mistake.

Sentencing Details

To date, of the fourteen individuals arrested as part of Operation Shark Fin, seven, including a former FDA Inspector, have pled guilty and seven are negotiating pleas.

OPERATION BAD APPLE

Operation Bad Apple was developed by the Customs Port of San Francisco as an outgrowth of Operation Shark Fin. This operation was intended to measure the compliance with import requirements by companies importing foodstuffs into the United States and to take enforcement action against willful and repeat offenders. This operation was conducted with the assistance and cooperation of the FDA from July 21, 1997 through August 4, 1997, at the Port of San Francisco.

Selectivity criteria were developed to electronically notify the inspectors of imported foodstuff. During Operation Bad Apple, 1,026 shipments of merchandise matched these criteria. Based on the matches, 429 shipments containing 1,428 line items were targeted for examination. (A shipment containing more than one product will have a line item for each product.) The examinations resulted in the discovery of a total of 305 discrepancies. More than one discrepancy can be found after examination of a single line item. Thirty-three shipments were denied entry into the United States for not meeting FDA requirements. Thirteen civil penalties were issued against importers totaling approximately $200,000.

As a result of this operation, the Port of San Francisco has identified the top 10 high risk importers of foodstuffs into the San Francisco area. These importers are being monitored closely for compliance with FDA import requirements.

GENERAL SHIPPING COMPANY, ET AL.

An investigation by the Associate Special Agent in Charge, Newark, New Jersey office disclosed that corruption among FDA inspectors allowed for the illegal importation of tainted foodstuffs. In June 1988 information was received from a convicted smuggler of contaminated foodstuffs that he had bribed FDA inspectors to release imported food shipments. The conduits for the bribes were his Customhouse brokers.

An undercover investigation resulted in two Customhouse brokers pleading guilty to bribery charges. The brokers led Customs agents to three additional companies that were bribing FDA inspectors in order to release or avoid examination of contaminated foodstuffs. The investigation led to the conviction of the presidents of two companies. The third company president died prior to the unsealing of his indictment.

Two FDA inspectors receiving bribes from these companies agreed to plead guilty and cooperate with the government in an undercover capacity. In 1992, as a result of their cooperation, three importers of oriental foodstuffs pled guilty to charges of bribery and smuggling of food. Additional importers and FDA inspectors were also identified as being involved in illegal activity.

In 1994, an importer's conviction on 138 counts of smuggling and re-importing rejected food was largely overturned by the Third Circuit Court of Appeals who ruled, that to "defraud the U.S." in Title 18, United States Code, Section 545, means to "defraud the revenue" and since the false invoices were created to avoid inspection rather than defraud the revenue, the criteria for conviction were not met. The importer had created false invoices from "good" food packers when, in fact, he was buying the merchandise from suspected packers who would have caused the food to be inspected and not bypassed. The conviction on re-importing rejected food was, however, upheld and the conduct relating to the counts that were overturned was allowed as relevant conduct for sentencing purposes.

Finally, in December 1994, the last defendant, a former FDA inspector turned "food consultant" was convicted. In all, eleven individuals were either convicted or pled guilty during this investigation. The investigation unearthed several different schemes importers used to circumvent or defeat the inspection process. Subsequently, the FDA created an Inspector General's office.

Sentencing Details

T.P. MENON was sentenced to the maximum sentence under the Sentencing Guidelines of 8 months in prison and 3 years probation.

ROBERTO VACCARO the former USFDA supervisor was sentenced to 5 years 3 months in prison and fined $10,000.

VINCENT TAORMINA, the co-operating USFDA Inspector, was sentenced to 4 months in prison and 4 months house arrest. He was also fined $10,000.

JAMES MORAETIS, the co-operating USFDA supervisor, was sentenced to 6 months house arrest and placed on 5 years probation.

MARTIN SRODIN, a co-operating USFDA inspector, was sentenced to 2 hundred hours community service and was placed on 3 years probation.

FRANCO DOS SANTOS, an importer, was sentenced to 5 years probation and fined $25,000.

JOHN and ANGELO CAMMARANO, Customhouse brokers, were both sentenced to 1,000 hours community service to be served in 4 hour periods each week over 5 years. They were each fined $10,000 and surrendered their brokers licenses to U.S. Customs.

JAMES LEE, import manager at CHUNG KONG FOODS, was sentenced to 3 years probation and fined $1000.00.

WELLMAN WU, President of CHUNG KONG FOODS, was sentenced to 5 years probation and fined $50,000.

MARK HUANG, the former import manager at CHUNG KONG FOODS, was sentenced to 5 years probation and fined $50,000.

SIGMA INTERNATIONAL, ET AL.

A joint investigation was conducted by the Customs Special Agent in Charge, Tampa, Florida, office and the FDA, Office of Criminal Investigations, into a scheme by which Sigma International, a large scale importer, four of its officers and one of its foreign purchasing agents, illegally imported Indian processed shrimp, valued at approximately $4.5 million, via false and fraudulent documents. These documents were provided to the government in order to avoid compulsory FDA laboratory testing, as well as examination of the merchandise. The merchandise consisted of decomposed shrimp that had been chemically treated to mask the decomposition. This scheme was uncovered through information provided by an FDA inspector

after his review of entry documents and examination of shrimp imported by Sigma.

The company was soaking the decomposed Chinese shrimp, purchased in India, in a solution of chlorine and copper sulfate with the intent to deceive customers by passing off the shrimp as "fresh frozen." Sigma sold its shrimp to large shrimp processors who, in turn, sold it to supermarkets and restaurant chains through the U.S.

Sigma International and three of its officers were convicted by a jury on a variety of charges. Two additional defendants remain fugitives.

Sentencing Details

William Andrew WALTON, SIGMA's vice president, was convicted of twelve felonies and sentenced to 41 months imprisonment followed by 24 months of supervised release, and a $10,000 fine.

Charles STERNISHA, general manager of SIGMA's St. Petersburg, Florida plant where the chemical treatment of the shrimp took place prior to its sale, was convicted of five felonies and sentenced to 27 months imprisonment followed by 24 months supervised release and a $6,000 fine.

SIGMA INTERNATIONAL, INC., was convicted of twelve felony counts, sentenced to a fine of $1,000,000, ordered to pay $114,053 for costs of prosecution (approximately $34,000 of this amount related to costs U.S. Customs incurred in the storage of seized shrimp) and $44,463 as cost of restitution, and placed on a term of probation for 5 years. The judge further ordered SIGMA INTERNATIONAL, INC. to implement an internal program to detect violations of the law, and to submit to a number of unannounced visits and inspections.

Robert FIELDS, SIGMA's lead salesman in the International Division, was convicted on October 18, 1997, of four counts involving illegally selling decomposed, chemically treated shrimp (21 USC 333 - which were reduced to misdemeanor counts when the jury found that FIELDS' had not acted with the intent to defraud and mislead), was sentenced earlier on February 21, 1997 to two years probation and a $2,500 fine.

Yaw-Bin "Tony" HUANG, SIGMA INTERNATIONAL, INC.'s president, fled the United States prior to the indictment, and remains a fugitive.

Geogy KANNIKAL, SIGMA INTERNATIONAL's purchasing agent is a resident of Cochin, in southern India, and remains a fugitive.

FRESH SEA PRODUCTS, ET AL.

In March 1996 a commercial truck entered the Otay Mesa Commercial Inspection Station Facility from Tijuana, Mexico. The driver declared frozen fish as products of Mexico. An initial Customs inspection disclosed the fish products were from the Orient. Further examination of the fish by Customs and FDA inspectors revealed the fish were from shipments which had been rejected entry into the U.S. by the FDA in 1994. The FDA had originally rejected the shipment for import because it contained salmonella, botulism and filth. This shipment had been exported and stored in Mexico and then was attempted to be re-imported and sold to restaurants in the Los Angeles area. The shipment was ultimately seized and ordered destroyed. The company president pled guilty in federal court for introduction of adulterated food into the commerce of the United States.

Sentencing Details

Anthony ZAVALA, President of FRESH SEA PRODUCTS, pled guilty in Federal Court in July 1996 to the introduction of adulterated food into the commerce of the United States and was sentenced to 1 year probation and 50 hours community service.

SAEWOO INTERNATIONAL

This investigation involved a Korean importer who attempted to reintroduce Korean foodstuffs into the commerce of the United States after the product was refused entry by FDA inspectors due to a high filth content. The importer had agreed to destroy the shipment. It was determined, however, that he had attempted to substitute other foodstuffs for the contaminated products and sell the contaminated products to wholesale customers. The company pled guilty to one count of smuggling.

Sentencing Details

SAEWOO, entered into a corporate plea agreement in which the company pled guilty to one count of 18USC545 and was sentenced to 1 year of probation, a $6,200 fine and $1,600 in restitution to U.S. Customs for storage of the merchandise.

UNITED INTERNATIONAL BUSINESS IMPORT/EXPORT INC.

In 1994, the FDA denied entry through the Port of San Francisco of 780 cartons of contaminated rice sticks imported from Canada. The shipment was subsequently shipped in-bond to Blaine, Washington, for re-export to Canada. Examination of the shipment in Blaine revealed that the foodstuffs contained in the shipment were not the same as those examined by the FDA in San Francisco. Civil penalty action against the company is pending.

ONGOING INVESTIGATIONS

Currently there are several ongoing investigations involving the importation of tainted foodstuffs. Joint investigations are being conducted with the FDA, Office of Criminal Investigations. These investigations include such schemes as: the attempted re-importation of tainted foodstuffs that were denied entry and subsequently exported, switching of foodstuffs that were denied entry and were required to be exported and foodstuffs that were mislabeled to avoid mandatory FDA inspection and testing. These investigations are expected to result in criminal prosecutions in the future.

I can assure the Subcommittee that this will continue to be a priority area for Customs and that we will continue to work with FDA to develop and execute effective investigative operations targeting individuals and organizations involved in tainted foodstuff importations.

CONCLUSION

Madam Chairwoman this completes my prepared remarks. I will be happy to answer any questions Members of the Subcommittee might have regarding Customs investigative efforts. I am joined today by Mr. Philip Metzger of our Office of Field Operations. Mr. Metzger will take any questions you might have that go to specific import processing procedures.

STATEMENT OF
FORMER CUSTOMS BROKER

Before The
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Hearing On
THE SAFETY OF FOOD IMPORTS:
FRAUD & DECEPTION IN THE FOOD IMPORT PROCESS
September 10, 1998

★★★

Madam Chairman and Members of the Subcommittee:

At your request, I am here today to testify about fraud and deception in the food import process. Before I begin my testimony, I want to thank you and this Subcommittee for respecting my request to keep my identity protected during this hearing.

I retired in February 1998, after serving almost 20 years as a Customs Broker. As a Broker, I was responsible for expediting imported cargo through the U.S. Customs Service and other related federal agencies. I also assisted importers with ocean, truck, air, and rail transportation as well as their insurance needs. In addition, I advised importers on the many different agency requirements for each of their products. I serviced several hundred clients and shipments each month.

As you stated, Madam Chairman, I recently pleaded guilty to a felony in federal court in San Francisco in an ongoing federal investigation, and I am scheduled to be sentenced later this month. Consequently, I cannot discuss any details of the ongoing investigation or my case. I am appearing here voluntarily and out of a sense of duty to correct the mistakes of the past.

Today, I will discuss some of the various techniques used by unscrupulous importers to circumvent Food and Drug Administration and U.S. Customs Service laws and regulations. Specifically, I will focus my remarks on three segments of the food import process: inbound shipments, refused shipments, and penalties for violations of import regulations.

I. INBOUND SHIPMENTS

There are many ways in which importers can avoid food safety inspections and introduce unsafe food into this country. An importer's main objective is to get their cargo to their buyers as quickly as possible and if they are importing adulterated products, they want to avoid FDA and Customs inspection procedures. They look for ports that have lax examinations procedures. L.A.-Long Beach and New York are the two ports with the largest inbound volume and are considered to be the easiest ports of entry.

Importers and brokers know which ports have the weakest import controls – this leads to "port-shopping". For example, in the San Francisco area, the FDA inspectors are much tougher than the Customs inspectors, but in Los Angeles, the Customs inspectors are tougher on the importers than the FDA inspectors. It is much easier to import adulterated food through these ports than others because of the volume.

Imported food shipments may be inspected by the Customs Service, the USDA or the FDA and, in some cases, all three agencies may inspect the products. Customs inspectors are authorized to conduct either merchandise enforcement team (MET) exams or contraband enforcement team (CET) exams. Because these inspections are not focused on food safety, my experience has shown that these exams do very little to prevent adulterated food products from entering the United States.

MET exams are conducted to determine if products are properly classified. An importer normally knows from the broker that the incoming shipment is going to have a MET exam prior to the arrival of the shipment which is perfectly legal and is expected as part of regular business. This allows the unscrupulous importer, however, to develop a scheme to substitute products prior to the Customs examination. For example, the importer will designate a truck driver to pick-up the cargo, move the cargo to the importer's warehouse where the adulterated food is replaced with legal products, and the truck driver will then deliver the container to the Customs exam site.

Many times, the container does not have to be at the Customs exam site for a few hours. The truck driver could pick-up the container before lunch and deliver it to the exam site after lunch, thereby allowing the container to be out of the government's control for several hours. The truck driver also could take out the container late at night and deliver the container to the exam site early the next morning.

The primary focus of a CET exam is on detecting incoming shipments of illegal drugs. As a result, these exams have no affect on importers who are shipping adulterated food products. For example, a shipment of rice-sticks, which is on automatic detention, may be shown on the manifest as noodles. If a Customs inspector opens the container and the boxes are labeled noodles, the manifest shows noodles, and there are no drugs in the container, the shipment will be cleared for entry into the United States.

When the FDA decides to inspect or sample imported food products, it will normally take place at the importer's premises. The importer is required to keep the product intact from the time it leaves the port until the FDA approves its release into U.S. commerce. Importers can take the products out of the shipping container and place them in their warehouse, but they are supposed to keep the products completely intact. However, it is very easy for importers to substitute products before FDA inspectors arrive. In some cases, the importer has from two to four weeks to prepare for the FDA's arrival. This allows the importer to sell the adulterated products and replace them with legal food products from a subsequent shipment – all before the FDA inspectors arrive.

Unscrupulous importers typically import large amounts of products that will not pass FDA inspection. In order to get these products through FDA inspections, importers will use a "banking" scheme. This is how banking is used to avoid inspection procedures and import unsafe food into the country. Importers will import some food items (referred to as "double clean") that will pass FDA inspection and store the items in their warehouses. When FDA arrives to inspect a shipment, the importer will provide the FDA food products from the good shipment. Once these items pass inspection, the importer can reuse these items for future FDA inspections. Depending on the shelf-life of the products, importers can use this scheme for several months to several years.

The automatic detention procedures also present importers with an opportunity to avoid food safety inspections. If the FDA finds imported foods that are adulterated or problematic, the FDA may place these products on automatic detention. This means that the FDA will not spend the time or the effort to sample the products, but will have the importers supply their own samples to a private laboratory and have those reports turned into the FDA to prove that the products are not adulterated.

Many importers prefer to have their products on automatic detention because they have control over the products. Importers prefer automatic detention because the laboratory reports are coming from private laboratories that are chosen by the importers rather than the FDA. Importers can submit as many samples as they like to the private laboratories for testing until they get a sample that will pass FDA's approval. In some cases, importers may actually select the food products to give the laboratory technicians for sampling. The food products supplied by the importers may not even be from the proper shipment.

II. REFUSED SHIPMENTS

Even when food shipments are rejected and found to be adulterated, the current system still allows importers to sell that unsafe food. If the FDA finds that a food shipment is adulterated and refuses entry, the importer has three options. First, he may recondition the products to bring them into compliance; second, he may destroy the products; or third, he may re-export the shipments. Importers need to sell the merchandise or may have already sold the merchandise so they will use various schemes to fake the destruction or re-export of the adulterated food.

Importers, for example, may fill containers with trash or some other item but not the adulterated food products that FDA has refused entry. When the truck driver arrives at the destruction site, the inspector may only weigh the container without examining the contents of the container. The importer may stack a few boxes of the refused product in the rear of the truck, thereby losing only a fraction of the original product. There also are importers who know the Customs inspectors very well and these inspectors may just sign-off on the destruction documents without doing any verification. In addition, there are no sanctions against importers if they get caught destroying the wrong product. The truck driver can always say that he made a mistake and picked up the wrong item.

Customs has very few controls over the re-exportation of refused food shipments. Importers may present Customs with different products to be re-exported than the products that were refused entry. Importers also may export products, repackage them, and try to import them again. Importers may even try another port.

Customs normally examines cargo that is destined for particular countries or a specific commodity, such as computer parts or automobiles. There is very little effort put into examining imported food products that have been refused entry into the United States. Here again, truck drivers control the cargo. Exporters can load anything they wish into a container and truck drivers can easily circumvent the entire process by delivering the cargo to the port at the last moment as the vessel is being loaded after an export exam as taken place.

III. PENALTIES

The penalty system used by Customs and the FDA to sanction importers when they try to bring unsafe food into the country is ineffective. Most penalties imposed are just written off as the cost of doing business.

During my experience as a Customs Broker, penalties levied by the U.S. Customs Service against importers did not serve as a deterrent for attempting to bring adulterated products into the United States. In fact, virtually every time importers were sanctioned, they were able to successfully get Customs to mitigate the penalties. Importers often say it was a mistake in order to deflect the blame for any violations or may go as far as having false fire or police reports presented to Customs to show that the products were either destroyed or stolen.

That concludes my statement, and I will try to answer any questions that you may have.

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STATEMENT OF SENATOR DANIEL K. AKAKA
SUBCOMMITTEE ON PERMANENT INVESTIGATIONS
SEPTEMBER 24, 1998

Senator Collins, I commend you for your diligence in pursuing the issue of food safety of imported foods. For the past 14 months , the Permanent Subcommittee on Investigations has undertaken an important task that I hope will lead to the reduction in health risks to American consumers from imported foods.

I am pleased to join you today in welcoming our distinguished colleagues: Senator Coverdell, Senator Mikulski, and Senator Kennedy, all of whom have introduced legislation relating to the importation of food and the safety of these imports, as well as Senator Harkin, the ranking member of the Senate Agriculture Committee. I look forward to receiving their testimony and that of our other witnesses today and tomorrow. I am confident the witnesses's testimony will assist us in further identifying the appropriate federal role in ensuring imported food safety.

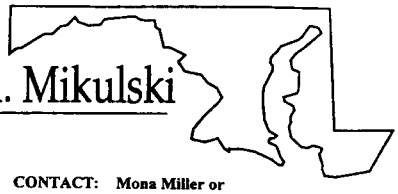
I must add that as a Senator representing Hawaii, which is envied for its pineapples, papayas, mangoes, bananas, and other tropical fruits, I obviously prefer American produce over foreign agricultural products. Our previous hearings have explored the problems associated with foodborne illnesses. We heard from expert witnesses testifying on inadequate entry-control systems for imported food. We have seen that federal efforts to ensure the safe importation of foods are unreliable and inconsistent according to a study by the General Accounting Office, and we learned that fraud and deceit were commonplace problems.

One problem area that has yet to be explored fully are pesticides banned in the United States that are still being used overseas. As we develop a comprehensive approach to the importation of food, we cannot forget about unsafe levels of pesticides and/or chemical residues found in imported foods.

Nor can we forget that America's consumers are not the only ones at risk. America's farmers suffer as well. Every time a pesticide is banned in the United States because of health reasons, our farmers must turn to alternative farming practices, which are often more expensive. Yet the farmers overseas do not operate under the same restrictions and the FDA, which is responsible for the safety of most imported foods, can only provide visual inspection of these items.

The American public deserves produce that is fresh and healthy--free from harmful pesticides, parasites, microorganisms, and unsanitary conditions. Again, I thank Senator Collins for undertaking this massive investigation and for holding this series of hearings.

News From
U.S. Senator Barbara A. Mikulski
Democrat from Maryland



FOR IMMEDIATE RELEASE
September 24, 1998

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TESTIMONY OF SENATOR BARBARA A. MIKULSKI
THE SAFETY OF IMPORTED FOOD ACT
SENATE SUBCOMMITTEE ON INVESTIGATIONS

"Madam Chair, I am very pleased that the Investigations Subcommittee is reviewing the safety of imported food. This is a very important and very timely issue; thank you for conducting this hearing on Congressional remedies. The health of Americans is not something to take chances with. It is important that we make food safety a top priority.

Every person should have confidence that their food is fit to eat. And we should be confident that imported food is as safe as food produced in this country. Our food supply has gone global, so we need to have global food safety.

We import growing quantities of fresh fruits and vegetables, seafood, and many other foods. In the past seven years, the amount of food imported into the U.S. has more than doubled. It is expected to increase another 33% by the year 2002. Out of all the produce we eat, 40% of it is imported.

Foreign produce that crosses our borders must be as safe as any food grown and processed in the U.S.A. Cars can't be imported unless they meet U.S. safety requirements. Prescription drugs can't be imported unless they meet FDA regulations. You shouldn't be able to import food that isn't up to U.S. standards either.

I am proud to be the sponsor of the "Safety of Imported Food Act of 1998" because it will provide the American people with safer imported foods. It gives FDA the authority to ban imported food from the U.S. if it was handled under unsanitary conditions or was not subject to a food safety system that meets the U.S. level of protection. In short, the bill will save lives.

THE PROBLEM

We have been put on alert by recent cases of foodborne illness. Michigan schoolchildren were sickened by imported strawberries contaminated with Hepatitis A. There have been widespread reports of cyclospora from imported raspberries. In Maryland, 130 cases of foodborne outbreaks were reported last year. That is over double the amount just ten years earlier.

Foodborne illnesses do not know state boundaries. An outbreak can occur anywhere, and it can occur in almost any food. Foods that we consider healthy are now causing sickness and even death. Fruits and vegetables, cereal and juices have all been associated with foodborne illness in the past few years.

The impact of unsafe food is staggering. As many as 81 million Americans become ill each year and over 9,000 die as a result of food-related illnesses. $3 billion is spent in hospitalization. Added to that are the losses in productivity. And it is our children and seniors who suffer the most. Most of food-related deaths occur in these two populations.

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FDA's current system of testing import samples at ports-of-entry does not protect Americans. It is ineffective and resource-intensive. The quantity of imported foods continues to increase. Less than 2% of imported food is being inspected under the current system. And when it is inspected, FDA can't always tell if the food is contaminated. Many contaminants cannot be detected without laboratory testing. And by the time tests are performed, many perishable foods will have spoiled. Also, FDA's authority to ban imports of food once there has been an outbreak only addresses the problem when it is too late to prevent any injury.

THE SAFETY OF IMPORTED FOODS ACT

Senator Kennedy's and my bill gives FDA the authority to ban imported food from the U.S. if it was handled under unsanitary conditions or was not subject to controls that meet the U.S. level of protection. The bill also allows the FDA to ban foods coming from places that deny the FDA the right to inspect their production process. The Secretary of Health and Human Services is required to develop a plan for the implementation of this authority upon passage of the bill.

The "Safety of Imported Food Act" improves the imported food process of the FDA and aims at preventing foodborne illness of all imported foods regulated by the FDA. It places the emphasis on the underlying food system of control at the food source, a more preventive means of addressing food safety. It focuses on the conditions that cause problems rather than the problem once it has occurred. By allowing FDA to consider the food safety system in place, the bill provides the means by which FDA can use its limited resources more efficiently.

There are several things this bill does not do. It does not shut our borders or immediately deny entry of imported food upon enactment. It does not require inspections or access for inspections without consent. In fact, it does not create any new inspection authority, either foreign or domestic.

The bill is short, but what it will achieve is significant. It will provide FDA with authority to ensure that all imported foods meet the U.S. level of protection, consistent with rights and obligations under international trade agreements. It provides FDA with a more effective enforcement tool and the ability to use its resources more effectively. Under the bill, foreign producers will have an incentive to upgrade their food safety systems. Most importantly, the bill will provide the American public with greater assurance that imported foods meet the same safety standards as do foods produced in the U.S.

Although recent outbreaks have scared us into jump-starting efforts to do more to protect our nation's food supply, no single step will solve the problem. We must look at ways to increase FDA's resources, eliminate internal weaknesses, and improve its regulatory authority.

This is why I support the President's Food Safety Initiative and I cosponsored an amendment that allocated an additional $66 million dollars for that Initiative.

My goal is to strengthen the food supply, whatever the source of the food may be. I pledge my commitment to fight for ways to make American's food supply safer. This bill is an important step in that direction.

CONCLUSION

Madam Chair, I would like to thank you again for conducting hearings on this very serious problem. These hearings are an important step. But the next step is taking action.

Yesterday, the Labor and Human Resources Committee voted to approve Dr. Jane Henney's nomination as FDA Commissioner. This position has been vacant for over a year. It is important that we give this agency permanent leadership so that this critical issue is addressed. Additional funding and this legislation should be approved during this Congress. If we cannot pass our bill this year, we need to develop a joint strategy between Congress and the new FDA commissioner for quick resolution next year.

Thank you again for giving me the opportunity to testify. I invite you to work with us on the solutions. "

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TESTIMONY OF SENATOR EDWARD KENNEDY
BEFORE THE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

For Immediate Release
September 24, 1998

Contact: Jim Manley
(202) 224-2633

I commend the subcommittee for its leadership on the important issue of food safety. Protecting the nation's food supply deserves high priority and is one of the basic responsibilities of Congress and the Administration.

In recent years the adequacy of current safeguards for food safety has come increasingly into question. An alarming surge has occurred in outbreaks of foodborne illnesses in recent years. Nearly every second of every hour of every day, someone in the United States is stricken with food poisoning. Each year, foodborne illnesses affect up to 80 million citizens, causing 9,000 deaths and costing an estimated $37 billion for health care and lost productivity.

Recent outbreaks have received national attention, including hepatitis A in frozen strawberries; cyclospora in raspberries; salmonella in ice cream and egg products; E. coli in fruit juice and hamburger--and these are just the tip of the iceberg.

The Centers for Disease Control attributes this surge to several factors, including changes in behavior, in technology, and in industry; the inadequacy of public health rules; and increased resistance of disease-causing bacteria and other organisms.

In addition, one of the most important causes is the rising number of imports from countries that do not have adequate procedures in place to assure the safety of their food products. Today, 33% of the fresh fruits and 12% of the fresh vegetables consumed in the United States are imported. And, the quantity of imports continues to rise by 25% a year.

With food imports soaring, it is essential for regulatory agencies to have the resources necessary to prevent and combat foodborne illnesses. I strongly support increased funding for President Clinton's Food Safety Initiative, and I hope that the Appropriations Committee will do all it can to include such funding in its FY 1999 bill.

But additional resources are only part of the issue. Congress must also give FDA the statutory tools to monitor the nation's food supply more effectively.

I commend Senator Collins for asking the GAO to study what is currently being done to ensure that food imports are safe. The findings are very troubling. Clearly, FDA can do a better job of managing its inspection of imports. But unlike the Department of Agriculture, FDA does not have the authority to require other countries to adapt adequate safety procedures for exports to the United States. We should not be willing to compromise our standards for food safety and food quality, wherever the food is produced.

The GAO report also found that inadequate resources prevent FDA from keeping up with the soaring number of imports each year.

S. 1707, which Senator Mikulski and I are sponsoring, addresses concerns raised in the GAO report. Our proposal would give FDA the authority it needs to prevent food imports from countries, if they fail to meet the safety and quality requirements for food produced in the United States.

Our proposal would also change the way FDA regulates food imports. FDA should be able to consider the safety systems in other countries, and assess the adequacy of those systems before the exports arrive at our borders. This procedure is much more efficient and effective than the current method of taking random samples of food imports as they arrive in this country. This new method will help FDA use its limited resources more effectively.

FDA urgently needs these better tools. Families across the country deserve to have confidence that the food they eat is safe, no matter where it is produced.

Again, I commend the subcommittee for its leadership on this issue. I look forward to working with you to achieve these essential goals, and I hope we can act on this legislation before Congress adjourns for the year.

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http://www.senate.gov/~harkin/ (202) 224-3254

FOR IMMEDIATE RELEASE:
September 24, 1998

Contact: Patrick Dorton/Christopher Moody

Hearing on the Safety of Imported Produce
September 24, 1998

U.S. Senator Tom Harkin (D-IA), the ranking Democrat on the Senate Agriculture Committee and a senior member of the Labor and Human Resources Committee, has been a leader in the Senate encouraging action to ensure the safety of our nation's food supply.

"Good morning. I am pleased to be with you this morning to talk about the growing concern Americans have about the safety of their food supply. Last year we had the largest recall of ground beef in history, and schoolchildren were sickened from contaminated strawberries. This year, in June alone, we had 12 major outbreaks or recalls from contaminated food. This summer a young girl died from an infection with *E. coli* O157-H7, which may have been linked to contaminated ground beef.

"A new survey, released this week in Des Moines, shows that Americans are more concerned about food safety than about crime prevention or even water quality. Their principle food safety concern was *E. coli* O157-H7, with 91% of them saying they were "concerned," or "very concerned," about this pathogen. Illnesses from this organism have been linked to a number of different fresh fruit and vegetable products, both domestically and internationally. Consumers expect the government and industry to respond to these concerns.

"I commend the Chairwoman and Ranking Member for holding this series of hearings to highlight the hazards Americans face from imported fruits and vegetables, and the need for Congressional action. I think that Congress has much work to do to help ensure the safety of the American food supply . But unfortunately, this Congress has been, with few exceptions, unresponsive in addressing critical issues of food safety. With the exception of this subcommittee, no other committee, including the Labor Committee and the Agriculture Committee, has held a hearing or mark up this year on any of the dozen food safety bills before Congress.

"Last October, I introduced a bill, S. 1264, The Food Safety Enforcement Enhancement Act, which would grant the Secretary of Agriculture the authority to recall adulterated meat and poultry products, and to impose civil fines on processors who violate federal meat and poultry safety statutes.

"Industry has argued that these enforcement tools aren't necessary because USDA has a number of options available to enforce safety laws. The Department can shut down a plant, or can seek a criminal conviction. But in shutting down a plant, minimum-wage workers are denied their livelihoods along with management. And, in a HACCP environment, systems errors that result in unsafe food may not be intentional. Civil penalties in this case are the more appropriate incentive to improve practices, than are criminal sanctions.

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"Industry argues that mandatory recall authority isn't warranted since industry complies voluntarily. This isn't always true, but if it were, why would responsible players oppose an authority that would serve only as insurance against the few bad actors? This bill should have been debated in the Agriculture Committee, and on the Senate floor.

"One hard-fought, yet tenuous victory in the fight for safer food came earlier this year during the debate on Agricultural Appropriations. Proposed within the FY99 budget was the Food Safety Initiative— $96 million in new spending for USDA and FDA, with twenty program areas to improve the safety of the American food supply. Although I was disappointed that we could not fund the entire amount, I was pleased that the Senate passed, by a vote of 65-34, an amendment I offered with Senators Leahy, Kennedy, Torricelli, Durbin, Wellstone, Mikulski, and Murray, which restored $66 million in funding for the Food Safety Initiative. I hope that all of us who voted for that amendment on the Senate floor will continue to fight for that funding level in conference, where it is threatened. Certainly, we can find the money to address issues, such as food safety which are of such overwhelming concern to American consumers.

"I also share with the Distinguished Senator from Maine a concern about the safety of fresh fruits and vegetables. I have sponsored language in this year's appropriation for the National Institutes of Health to fund the National Cancer Institute in promoting the Five-A-Day message, encouraging people to eat five servings of fruits and vegetables each day. This recommendation is intended to promote good health. I want to make sure that the foods we recommend are safe.

"As Americans heed the advice to eat more of these fruits and vegetables, they demand commodities out of season, or specialty products, and can enjoy, even in wintertime, strawberries that were grown in the southern hemisphere. The number of imports has soared, as we have seen. The future of food safety rests in production systems in which safety is built in.

"Hazard Analysis and Critical Control Points, HACCP, is a way of thinking about risk, and of implementing preventive strategies, all the time. HACCP systems, properly implemented, can assure that any type of food is grown, harvested, processed and shipped in ways that minimize or eliminate all manner of known and unknown hazards.
I supported the implementation of the Pathogen Reduction/ HACCP plan for meat and poultry, and I support this type of system for all other foods as well. FDA implemented processing standards for dairy and canned foods some time ago, and recently mandated HACCP systems for seafood. FDA is currently working toward similar systems for juices and sprouts, and has partnered constructively with industry to develop voluntary guidelines for growing, harvesting and processing other types of produce. These voluntary guidelines incorporate current knowledge about hazards, and suggest some reasonable areas for further study. While the guidelines are not, themselves, HACCP systems, they move in the right direction.

"Agriculture is America's largest industry, employing more than 22 million people. In my home state of Iowa, agriculture is the backbone of our economy, providing billions of dollars in income to farmers, ranchers, and rural communities. States like Iowa cannot afford to have the American public questioning the safety of the food one their dinner tables. This is not only a public health issue, but an economic issue. That is why our work here is so important.

"As I stated earlier, Congress has much work to do on food safety. Words must be coupled with action. I certainly hope that in the coming weeks Congress supports the food safety funds that are desperately needed. I also hope that this subcommittee, the Labor Committee and the Agriculture Committee will work together in the next Congress to address this issue with the level of commitment the American public expects."

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Statement of Raymond W. Kelly
Commissioner
United States Customs Service
Before the
United States Senate
Committee on Government Affairs
Permanent Subcommittee on Investigations
September 24, 1998

Madam Chairwoman and Members of the Subcommittee, I am pleased to be here today to discuss Customs' efforts, both internally and in cooperation with the Food and Drug Administration (FDA), to address the importation of tainted food. I want to assure you that I, and all of the employees of the Customs Service, share the level of concern raised by the Subcommittee over the safety of food entering this country. Those involved in schemes to knowingly violate U.S. Food Safety laws are driven by the same motives as those engaged in narcotics smuggling - greed. Just as we attack illegal drug smuggling, the U.S. Customs Service will be vigilant in our efforts to keep unsafe, imported food products from showing up in stores and restaurants throughout our nation.

As Deputy Assistant Commissioner of Investigations Richard Hoglund testified at your previous hearing, the United States Customs Service enforces more than 400 laws for more than 40 U.S. agencies including the Food and Drug Administration and the U.S. Department of Agriculture. Approximately 20-25 percent of the other government agency work that we conduct is in the enforcement of the Food and Drug Administration's statutes and regulations. Customs enforcement of laws that prohibit the importation and exportation, or seizure of merchandise is guided by the direction and orders of administering agencies. We are proud of the service we provide because we know how important food safety is to the American people. Customs must utilize existing resources which are already stretched to carry out the enforcement of these laws in addition to our primary mission which is the interdiction of illegal narcotics.

Preventing the importation of tainted food presents a unique challenge and I will briefly review what actions we have or intend to take to ensure that American citizens are protected from contaminated foods. Unlike the concealment of illegal narcotics in false compartments or within otherwise legitimate

merchandise, tainted food can come into the country in plain sight. However, it is difficult to determine, upon initial examination, which imported food will fail FDA standards. This morning in my remarks, I will address the four questions which the Subcommittee posed to me in your invitation letter of August 20th. Those questions are (1) What are the deficiencies in the current food importing process? (2) What specific recommendations does the Customs Service have to improve the safety of imported food? (3) What specific actions is the Customs Service taking in response to the April, 1998 GAO report on food safety? And (4) What other changes should be considered to improve the food import process?

PROCESS IMPROVEMENT INITIATIVES

In response to question one, as you are aware, through Operation Bad Apple, the Customs Service has identified a number of areas in the food importing process that could be better handled. We have reviewed the weaknesses identified by the port of San Francisco and have found that some of these were allegations made by brokers, some were suppositions made by the port, and others were comments on FDA processes of detention and seizure. These short comings can be broken down into three subgroups (1) cargo control (2) coordination issues and (3) sanctions or penalties. Cargo control deficiencies result in such schemes as "Banking" and container switching and also include issues related to the proper destruction of tainted food imports. Coordination problems include the difficulty that Customs and the FDA have had in sharing relevant information on suspect imports. With regard to sanctions, the existing penalty structure may not be strong enough to effectively deter non-compliant importers.

In response to question two, there are a number of recommendations Customs has been considering to improve the safety of imported food. We believe it is necessary to establish better control over the movement of suspect cargo through the use of technologies such as discreet transponders attached to containers. We feel it is also necessary to improve current methods of targeting violative importers through expanded manipulation of existing data. On the regulatory front, we would like to see the FDA's notice of refusal also serve as Custom's notice of delivery. This would significantly cut down on the

amount of time necessary to process non-compliant importers. And finally, we think a national interagency team comprised of FDA representatives and Customs trade compliance experts should be established to coordinate our efforts on this front.

In response to question three regarding the GAO findings on food safety, the Customs Service is taking action on those recommendations which affect our responsibilities. This includes (1) better coordination with FDA (2)targeting and cargo control (3) using unique identifiers (4) destroying and/or exporting tainted food, and (5) more appropriate assessment of sanctions against violators. I will address each of those areas in my testimony.

COORDINATION

With regard to coordination with FDA, GAO cited notices of refusal by FDA that were not received or acted upon by the Customs Service. In response to that concern, we are reprogramming our database to extract FDA-issued refusal notices. This will allow us to have a clear list of FDA refused actions without relying on paper copies of such notices transmitted through the mail. As I indicated, we are seeking regulatory authority to have the FDA notice of refusal serve as the Customs redelivery notice which, in so doing, will automatically obligate the Customs surety bond. This will eliminate the need for Customs to send its own notice for each FDA refusal and will facilitate the enforcement process.

TARGETING AND CARGO CONTROL

With respect to targeting and cargo control, Customs is working with FDA to target importers, high risk products, and FDA violative shipments nationally. As we have previously testified, the results of Operation Bad Apple continue to help us target shipments of importers who are involved in schemes to avoid inspection. During Operation Bad Apple, we examined 429 shipments of which 16 percent were found to have discrepancies. This discrepancy rate does not mean that 16 percent of the shipments failed laboratory testing. What it does indicate is that there are discrepancies that can impact Customs targeting of FDA regulated commodities. For example, six countries comprised 40 percent of the detected violations which permits us to focus

on importers and commodities from these high-risk countries.

Based on our experience with Operation Bad Apple, Customs and FDA will collaborate on a target list of importers and products for which national initiatives will be established to detect and control FDA-violative shipments. We will use the Customs automated targeting system to subject the shipments to heightened levels of examination and scrutiny. We are more effectively coordinating our efforts at several ports and are experiencing increased success at those ports where interagency teams have been formed. We will look to expand this task force approach.

Although we want to better control food shipments, current resource limitations prevent us from enforcing the laws in the most effective way possible. The FDA does not have its own storage facilities to sample and test food shipments. Accordingly, importers may move their shipments to their own facilities pending FDA final action. The expanded use of Centralized Examination Stations (CES) or bonded warehouses has been suggested. The use of either presents different problems for the Customs Service. There are simply not enough examination stations at this time and those that exist are not equipped with the necessary refrigerated rooms for perishable food to provide the needed storage. Despite these dilemmas, Customs will continue to explore with FDA the use of CESs for Customs sampling of shipments of certain violative and targeted importers.

As for bonded warehouses, under current law Customs does not have the authority to require a bonded warehouse entry. In addition, there are operational disincentives peculiar to bonded warehouses. Even if we could require their use, Customs does not have the resources to provide continuous supervision over them. As a result, importers would still have access to their shipments and we would be unable to assure that switching of merchandise awaiting FDA examination would not still occur.

UNIQUE IDENTIFIERS

Customs is developing enhanced technology that will allow us to track shipping containers from the place of unlading to the Centralized Examination Station. New technology as the aforementioned transponders, will help us track shipping

containers from the place of unlading to the examination station. In the coming months, we will test this technology at ports with high volumes of suspect food shipments.

DESTRUCTION AND/OR EXPORTATION OF TAINTED FOODS

Now, when the FDA refuses a food shipment, we work with the importer, under the law, to destroy or ensure exportation of that shipment. Should an importer select destruction as an option, the destruction does not necessarily take place at a Customs port of entry. The destruction may occur, for example, at a landfill or at an incineration plant. It is difficult to determine whether a shipment presented for destruction is the actual shipment that was imported and tested because the shipment remained in the physical control of the importer. Another challenge we face is that every port does not have the resources to send an inspector to witness every destruction. Some of our ports do witness all destructions. We estimate that there are approximately 10,000 FDA required destructions conducted in a year.

If an importer selects exportation as an option, as stated above Customs is working with FDA to target high-risk shipments for heightened levels of verification of exportation or destruction. Customs will disseminate examination guidelines along with designated targets to all of our inspection personnel to aid in this process. Once we have confirmed the exportation of food that has failed testing, the possibility remains that the importer may try to re-import the food. This is a complicated issue for FDA and us, and we will consult with FDA to review their policy on this subject and do all that we can to ensure that rejected food is not brought back into the United States.

SANCTIONS

With regard to sanctions, we are seeking regulatory authority in these cases to demand more than three times the value in liquidated damages. When an importer fails to destroy or export an FDA-refused product, Customs currently assess a claim for liquidated damages in an amount equal to three times the entered value of the refused merchandise. In addition, for repeat violators, we will consider requiring a separate bond for each shipment entered by the high-risk importers.

In addition to liquidated damages under the import bond, Customs has the authority to assess monetary penalties equal to the domestic or market value of the violative merchandise. These penalties can be and have been assessed in situations where FDA-refused products failed to be exported or destroyed, including those instances where substitution of the refused product is discovered. We will work with FDA to pursue a more aggressive use of monetary penalties.

While Customs does have the authority to immediately seize food declared by FDA to be tainted, the statute under which seizure can be made requires forfeiture to be declared by the District Court. This is a cumbersome process. By contrast, the statute under which FDA refuses admission granting the importer a 90-day period to export or destroy that merchandise is less cumbersome. Due to the complicated procedure in the District Court, FDA generally allows export or destruction.

In cases of switching merchandise, Customs can seize the substituted goods on the basis that they will aid in the illegal importation of the refused violative product. Customs also has authority to seize conveyances that are used to aid in the introduction of any violative product into the commerce.

Finally, we are continuing our investigative efforts into food safety violations. As we inquire into the activities of importers, our investigative efforts often result in indictments, arrests, and convictions of , and fines against those making false statements, smuggling, or conspiring against the United States. The most serious violations and repeat violators have been and will continue to be criminally prosecuted. Various criminal statutes related to smuggling, false statements, and conspiracy are available for use against serious or repetitive violators.

Since September 1993, Customs has conducted some 134 criminal investigations related to the importation of tainted or prohibited food. Currently we are conducting several ongoing criminal investigations in conjunction with the FDA. These investigations involve such schemes as the attempted re-importation of tainted food which had originally been denied entry in the United States, as well as foods that have been mislabeled to avoid mandatory FDA inspection. We intend to pursue our investigative activities in this area and work closely with the Department of Justice to ensure those involved in

illegal activities are prosecuted to the full extent of the law.

Finally, in response to question four, I will reiterate a point I made earlier. Our role in the issue before the Subcommittee today is not that of the "lead" agency, but rather as an agency brought into assist with the enforcement of policy initiated by another agency. In this regard, I will defer to the expertise of the FDA in determining other necessary changes to improve the food import process.

CONCLUSION

As I conclude my testimony, I can assure the Subcommittee that the safety of the nation's food supply is important to the U.S. Customs Service. We will continue to do everything we can with existing resources and in cooperation with FDA to keep Americans safe from tainted and contaminated foods. We will target individuals and organizations that persist in importing tainted food. We will also continue to explore changes to the bond regulations that will provide more stringent deterrents.

Madam Chairwoman, this completes my prepared remarks. I am accompanied today by Mr. Philip Metzger of our Office of Field Operations, who also appeared before the Subcommittee at your last hearing. We will be happy to answer any questions you or the members of the Subcommittee may have.

STATEMENT OF
THOMAS J. BILLY, ADMINISTRATOR
FOOD SAFETY AND INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE
BEFORE THE
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS
SEPTEMBER 24, 1998

Madame Chairwoman and Members of the Subcommittee, I appreciate having the opportunity to appear before you today to discuss the inspection system used by USDA's Food Safety and Inspection Service for meat, poultry, and egg products imported into this country. This inspection system ensures that all imported meat, poultry, and egg products meet United States food safety standards—the highest food safety standards in the world. Today, I am accompanied by Dr. Mark Mina, Deputy Administrator for Field Operations and Ms. Margaret Glavin, Deputy Administrator for the Office of Policy, Program Development and Evaluation.

Ensuring the safety of the foods Americans eat is a priority of the Clinton Administration. The President's Food Safety Initiative announced in January 1997 established a coordinated effort by the USDA and the Department of Health and Human Services to ensure the safety of a wider variety of food products from a broader range of hazards. FSIS is continually assessing both its domestic and import inspection programs to identify changes that will improve the safety of meat, poultry, and egg products and to reduce the incidence of foodborne illness attributed to these products.

I believe we have made significant progress in establishing a structure for major improvements in food safety. The 1994 USDA reorganization separated the food safety regulatory function from the marketing function, effectively eliminating any questions from years past about the appearance of an intra-departmental conflict of interest. The reorganization legislation created the Office of the Under Secretary for Food Safety and mandated that the office be occupied by an Under Secretary who has a specific, proven public health or food safety background. These changes have enhanced USDA's public health focus and fortified food safety's presence within the department's broad mission.

The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act give FSIS the authority and the responsibility to inspect meat, poultry, and egg products on a continuous basis and set the food safety standards for these products. In requiring the continuous inspection and the meeting of set standards for domestic products, it is perfectly appropriate and perfectly consistent with our international trade agreements that FSIS demands and certifies that imports are likewise produced under conditions that achieve the same level of protection as U.S. established standards for food safety. When it comes to meat, poultry, or egg products, American consumers are provided the same level of protection, whether these foods are produced at a big plant or a small plant, whether they are produced domestically or abroad.

The amount of meat, poultry, and egg products imported into the U.S. is very small compared to U.S. produced products. Imported meat accounts for only about 7 percent of domestic consumption; imported poultry totals less than 1 percent; and imported egg products also total less than 1 percent. Not one pound of these imported products is permitted entry into the United States unless has it has undergone inspection in a system certified by FSIS as equivalent to the FSIS inspection system.

Only 37 countries have been certified as meeting our standards. Again, these are not "special" or lower standards; they are standards that U.S. packers and processors must meet. In general, inspection under an equivalent system means meeting U.S. standards for microbiological pathogens and chemical residues; it also means meeting all sanitation standards applicable to U.S. meat, poultry, and egg products plants. In addition, imported egg products (liquid, frozen, or dried eggs) must either arrive pasteurized or be transported directly to a U.S. egg products plant for pasteurization. And perhaps most importantly, all plants exporting meat and poultry to the U.S. must meet the requirements of the Hazard Analysis and Critical Control Points (HACCP) inspection system. I will discuss those requirements in greater detail later in my testimony.

Meat and poultry products consumed in the United States but originating abroad are the most heavily inspected food products in the world. As I noted, imported meat and poultry are required to be inspected under a foreign inspection system that FSIS has determined to be equivalent to our system. Then, upon arrival at a U.S. port of entry, all meat and poultry shipments undergo reinspection by FSIS. Almost all imported product, about 85 percent, then proceeds to a federally inspected meat or poultry plant for further processing, under the supervision of FSIS inspectors.

Before I discuss our import inspection program in more detail, I would like to briefly discuss the dramatic changes being instituted in our domestic meat and poultry inspection program. These changes directly impact foreign countries desiring to export product to the U.S., and the changes are significant. When the *E. coli* O157:H7 outbreak on the West Coast occurred in early 1993, a food processing system known as HACCP was not required for meat and poultry products. To improve the safety of meat and poultry products, we published a final rule in 1996, which is the centerpiece of our new regulatory system. This system is geared toward preventing problems before they occur rather than detecting problems after they occur. This new regulatory system is designed to significantly reduce the incidence of foodborne illness attributed to meat and poultry products, from either domestic or imported products.

The new rule (1) requires that all meat and poultry plants develop a system of preventive controls, known as HACCP, to improve the safety of their product, (2) sets pathogen reduction performance standards for *Salmonella* that slaughter plants and plants producing raw ground products must meet, (3) requires all meat and poultry plants to develop and implement written standard operating procedures for sanitation, and (4) requires meat and poultry slaughter plants to conduct microbial testing for generic *E. coli* to verify the adequacy of their process controls for the prevention of fecal contamination.

Implementation of the rule began on January 27, 1997, and will be completed by January 26, 2000 in every meat and poultry plant. All of the requirements in the rule--including the microbial testing--must be implemented by foreign inspection systems desiring to establish eligibility or to maintain their eligibility to export to the U.S.

Let me assure you that we are committed to ensuring that countries eligible to export meat and poultry products to the United States continue to meet requirements applicable to those required of domestic meat and poultry plants. In 1996, we informed the 37 countries eligible to export to the United States what the new requirements were and the deadlines for implementation. We then directed them to tell us in writing how they intended to meet the new requirements. After our concurrence with their plans, we are now verifying through audits that eligible countries are meeting the requirements.

DETERMINING EQUIVALENCE

I would like to turn now to how FSIS determines inspection system equivalence of foreign countries. FSIS uses a two-part process to determine that eligible foreign countries maintain inspection systems that are equivalent to the U.S. system.

The first part of the process, *document analysis,* is an evaluation of the country's laws, regulations, and other information pertaining to its inspection system. The document analysis focuses on five risk areas: contamination, disease, processing, residues, and economic fraud and compliance. Technical experts evaluate the information to assure that critical points in the five risk areas are addressed completely with respect to standards, activities, and resource allocations.

The second part of the process, *on-site reviews,* involves actual on-site visits to foreign countries, including randomly picked plants within the country, to ensure the country's inspection system is equivalent to the U.S. system. We don't just do this review once. In most cases, on-site reviews are conducted each year in all eligible countries.

During on-site reviews, an FSIS technical team visits the country to evaluate the five risk areas as well as other aspects of the inspection system, including plant facilities and equipment, laboratories, training programs, and in-plant inspection operations. If FSIS determines that the inspection system is equivalent to the U.S. system, the country becomes or remains eligible to export meat or poultry to the United States. The foreign country then provides FSIS with a list of plants the country has determined meet all the U.S. requirements. This list is continually updated by the responsible foreign officials.

NOT EQUIVALENT

If FSIS determines that a foreign country is not meeting standards equivalent to those of the United States, we take appropriate action. If the product from the country is determined to be a public health risk, FSIS immediately suspends the country's eligibility to export and refuses entry to any shipments that are in transit to the U.S. For example, in January of this year, FSIS suspended Paraguay from the eligible list because our audit of Paraguay's inspection program revealed serious problems with fecal contamination of

carcasses, the absence of an *E. coli* testing program, and general sanitation problems in all the plants that were visited.

If the issues are determined to be less serious, FSIS immediately initiates a conference call with the country's inspection officials and the country is provided with a copy of our audit report, which documents the problems found. For example, after being advised of audit findings earlier this year, Spain and Switzerland voluntarily delisted many of their plants certified to export to the U.S. These countries are now reviewing their inspection systems as a whole to ensure that national oversight of plants certified to export to the U.S. is working effectively.

REINSPECTION OF IMPORTS

As a further check on the effectiveness of an eligible country's inspection system, FSIS conducts product reinspection at 156 FSIS-approved import establishments. During 1997, about 75 inspectors carried out import reinspections.

When FSIS receives notice that a shipment is entering the U.S. for reinspection, FSIS enters information about the shipment into our centralized computer system called the Automated Import Information System (AIIS). The AIIS informs the inspector if the country, plant, and product are eligible for export to the United States; it also generates a reinspection assignment, based on the plant and country's compliance history for that specific product. Inspection results are later entered into the AIIS, helping to establish the level of reinspection for future shipments from the plant and the country.

During reinspection, inspectors check documents accompanying the product to assure the shipment is properly certified by the foreign country. Certificates identify products by country and plant of origin, destination, shipping marks, and amounts. The documents certify that the products received ante-mortem and post-mortem inspection under a system that is equivalent to U.S. inspection; that they are wholesome, not adulterated or misbranded; and that they otherwise comply with all U.S. requirements. Inspectors next examine each shipment for general condition and product labeling, and then conduct the reinspection assignments directed by the AIIS. When the AIIS directs that product samples be taken, product samples are randomly selected by inspectors. Samples are analyzed at FSIS laboratories for microbiological contamination, chemical residues, species verification, and product composition.

FSIS regulations require that all meat and poultry products imported into the U.S. bear the name of the country of origin on the packaging, which remains with the product to the retail level unless the product is further processed under U.S. inspection. We have all seen the canned hams in the supermarket clearly identified as a "Product of Denmark."

When the imported products has been passed for entry, the products are now deemed and treated as domestic articles under the Federal Meat Inspection Act and the Poultry Products Inspection Act. The 85 percent of imported meat and poultry that is further processed in U.S. plants ends up in such products as hot dogs, Polish sausage,

Texas chili, chicken noodle soup, TV dinners -- all processed products that are produced under U.S. inspection.

When a shipment passes reinspection it is released into U.S. commerce. If a shipment does not meet U.S. requirements, the containers are stamped "U.S. Refused Entry," and are officially controlled by FSIS. The importer has 45 days to have the product reexported, destroyed, or converted into animal food when appropriate. FSIS retains control over the rejected product until it is reexported or destroyed for human food purposes. If the importer chooses to reexport the product, the importer must provide documentation to FSIS that ensures that the product has been reexported. If the importer chooses to have the product destroyed or diverted to an animal food manufacturer, these actions must occur under FSIS supervision.

GAO RECOMMENDATION

In an April 1998 report, GAO affirmed that FSIS is doing a good job in its import inspection program. The report stated that by requiring foreign country equivalence, FSIS is able to devote its resources to verifying "the efficacy of these exporting countries' systems and thereby use its inspection resources more efficiently."

As with any regulatory program, however, there is always room for improvement. GAO suggested, for example, that one aspect of import reinspection was not as strongly risk-based as it could be. A recommendation was made that product samples collected at reinspection be based on "laboratory results and specific foods, foreign firms, and exporting countries" that pose the highest risk. Even though FSIS does focus its reinspection and testing resources on shipments from countries with a history of violations, GAO found that most of the violations are not related to food safety, but involve such things as wrong or missing shipping labels or incorrect weights. When our limited resources are used in that manner, GAO noted that there are fewer resources available for inspection of imported products that pose the greatest health risks from such factors as contamination and decomposition.

FSIS concurs that inspection must be risk-based. We are undertaking a review of our entire port of entry reinspection procedures, including sample selection, to determine changes that may be needed to improve the overall ability of our system to focus inspection resources on those products or processes posing the greatest public health risk. This action is consistent with our program-wide plan to use the results of risk assessments to redeploy our inspection resources to those areas across the farm to table continuum based on the level of risk to the public health. To the extent that imported products are identified as posing a higher degree of risk to consumers, we will reassign resources as needed. We believe this strategy will help us to better protect the health of American consumers.

In closing, I would like to say that we at FSIS are continually striving to improve our inspection system with the goal of minimizing the incidence of foodborne illness from the consumption of meat, poultry and egg products, whether those products are produced in the U.S. or a foreign country. Thank you for the opportunity to discuss FSIS' import inspection program.

STATEMENT BY

WILLIAM B. SCHULTZ

DEPUTY COMMISSIONER FOR POLICY

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. INTRODUCTION

Good morning, Madam Chairman, Members of the Committee. I am William B. Schultz, Deputy Commissioner for Policy, Food and Drug Administration (FDA or the Agency). With me today are Joseph Levitt, Director, Center for Food Safety and Applied Nutrition (CFSAN), and Gary Dykstra, Deputy Associate Commissioner for Regulatory Affairs (ORA). We appreciate the opportunity to participate in this hearing, and we thank you for the leadership and concern you have demonstrated on the issue of the safety of imported foods.

II. BACKGROUND

As you know, food safety has been a high priority of this Administration, as evidenced by the President's Food Safety Initiative and Produce Initiatives. We believe the reports you have requested from the General Accounting Office (GAO) and the three previous hearings you have held have provided added focus and clarity to this important issue.

Even though Americans enjoy one of the safest food supplies in the world, every year tens of millions of Americans become sick and thousands die from illnesses caused by both domestic and imported food. The increasing quantities of food that are imported into the United States has raised some significant questions about our ability to protect consumers from potential hazards. We agree with those who believe that our approach to the regulation of food imports needs to be updated to meet the demands of modern society. We also know that improving FDA's import

program will be a serious challenge. FDA's current program relies primarily on inspection and testing at the border to ensure that imported food products meet our food safety requirements. While this approach was sufficient at the turn of the century because relatively few foods were imported, today, we are seeing changes in food imports that necessitate changes in our approach. We believe that dramatic new approaches are called for, including improvements in the existing imported food program, new authorities to more efficiently implement the program, and a significant infusion of resources, as reflected in the Administration's budget for FY 1999.

In the remainder of my testimony I will describe our current import program and give some background on the President's two food safety initiatives, both of which strengthen our imported foods program. I then will move on to the GAO Report and the Agency's recommendations for improving how we fulfill our responsibility to assure the safety of imported foods.

III. FDA'S IMPORT PROGRAM

During the past 12 years, food imports have grown dramatically. In 1985, only approximately 950,000 line items[1] were offered for import into the United States. As the attached chart shows, that number more than tripled to over 3 million line item entries by 1998, and is expected to continue to increase.

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[1]A single entry may contain multiple line items of food offered for import. Each line item corresponds to a specific item on the invoice or shipping papers.

In addition, the nature of imported foods has changed. In the past, most imported products consisted of raw or bulk materials which were further processed into finished products in the United States. Currently, more and more food imports consist of finished, value added foods (e.g., cooked, ready-to-eat, quick frozen shrimp as opposed to raw shrimp for cooking/processing in this country). As products receive additional processing, the potential for the product becoming contaminated and a potential public health hazard increases. For example, the hazard associated with a microbial pathogen, such as Salmonella, in a ready-to-eat food is potentially greater than in a product that will be cooked before eaten. As we all know, fresh produce and seafood can pose additional risks, particularly with emerging pathogens. Today, 38 percent of fruit consumed by Americans, 12 percent of vegetables, and 50 percent of seafood are imported. As noted by the August 1998 report by the Institute of Medicine/National Research Council, *Ensuring Safe Food: From Production To Consumption*, (IOM/NRC Report), sample analysis is not adequate to detect many of the more serious risks from these microbiological hazards. To monitor adequately the safety of many imported foods, it has become necessary to understand and be able to evaluate the conditions under which they are grown, manufactured, and transported.

Meanwhile, the resources allocated to the inspection of imported foods have actually decreased. In 1992, we received approximately 1.1 million line items of imported foods and had 631 supported Full Time Equivalent employees (FTEs) to look at those items. By 1997, our line items more than doubled to approximately 2.7 million but budget limitations caused us to cut our supported FTEs to 565. Of these 565 FTEs, only 314 are what we refer to as "operational," with 112 actual investigators and 202 analyzing samples in the laboratories. (The others are support

staff, including those at headquarters.) In practice, this means that in 1992 we were able to physically inspect 8 percent of all imported foods. Today, the Agency physically inspects only 1.6 percent of imported food.

Since resources are limited, FDA sets its priorities by focusing on risk, and therefore, by placing an emphasis on the analysis of foods upon import for a variety of hazards, which include heavy metals, pesticides, chemical contaminants, natural toxins, allergens, pathogens, histamine in seafood, etc. The presence of some of these hazards can lead to illness or death. Given our risk-based strategy, FDA focuses its import activities on problem, product, and country. For example, a higher priority is given to low-acid canned foods to protect against potentially fatal botulism, as well as other ready-to-eat foods susceptible to pathogen contamination (such as Listeria monocytogenes and Salmonella), while a lower priority is given to issues less directly related to public health, such as minor labeling violations.

In recent years, FDA has implemented several enhancements to its program in response to the increase in imported foods. We have developed an automated screening system, which receives data via United States Custom Service (USCS) system, capable of electronically reviewing information submitted by filers. This system, Operational and Administrative System for Import Support (OASIS), has been operating in all FDA districts since October 1997. FDA uses OASIS to screen shipment information using a variety of risk-based criteria. These criteria include the type of product, the country of origin, the foreign manufacturer, and the foreign shipper. Criteria used in screening always includes a default examination rate, so that products that might

otherwise not meet any criteria triggering FDA review could randomly be considered for review. This default system ensures that every product offered for import has some possibility of being examined. OASIS determines whether a shipment may proceed into domestic commerce, needs further review, or must be detained.

Let me now explain briefly how the Agency's current import program works. Using the relatively new OASIS system, FDA reviews all food entries offered for import, either electronically or by staff evaluation. Based on this review, each entry is designated either a "May Proceed without FDA examination" or "FDA Review". After an "FDA Review," the product may be redesignated "May Proceed," selected for "Examination," identified for "Detention Without Physical Examination," or the filer can be told to submit additional documents before FDA can make an entry determination. Through this electronic review, approximately 55 percent of all FDA food line items are categorized as "May Proceed" and are admitted into domestic commerce within minutes. In FY 1997, of the 2.7 million food line items, approximately 1.5 million were categorized as "May Proceed" based on electronic screening.

The entries that do not receive a "May Proceed" are subject to additional review, and the filer may be required to submit paper documentation for the entry. FDA inspectors verify whether certain information submitted by the filer is accurate and determine if the product, country, shipper, importer, and/or manufacturer are the subject of an Import Alert.[2] The inspector will

[2]Products for which there is a basis to detain without physical examination are placed on an Import Alert. Import Alerts identify problem commodities, countries, and/or shippers and provide guidance to FDA field staff. Occasionally, FDA places products from an entire country

make a decision to release or detain the entry or to sample or conduct a field examination. When FDA detects the appearance of a violation, the Agency detains the product. Detention is intended to prevent the products from entering domestic commerce until the importer submits information to FDA that overcomes the appearance of a violation, or the products are brought into compliance with the law through reconditioning if this is appropriate. Where the importer fails to overcome the appearance of a violation or where detained products cannot be brought into compliance, FDA refuses admission of the products into the United States, and the products must be destroyed or re-exported, according to USCS regulations. FDA also can seize violative imported products, which involves a formal judicial action.

In addition to having the authority to refuse entry of an apparently violative import, FDA may detain products without physical examination when they consistently violate FDA requirements or when FDA has information that they are health hazards. The products of importers who frequently have presented violative products for import or who have tried to evade the law may be detained without physical examination. Under this control measure, all subsequent shipments of the suspect product may be detained upon import (not distributed in domestic commerce) until either the importer, shipper, producer, or a responsible agency of the exporting country provides information establishing, to FDA's satisfaction, that the shipment is in compliance.

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or region of a country on detention without physical examination when the violative conditions appear to be geographically widespread. Recent examples of country-wide Import Alerts include cheese from El Salvador due to a history of contamination with Salmonella, Escherichia coli, and Staphylococci aureus, and raspberries from Guatemala due to past outbreaks of Cyclosporasis.

By providing uniform entry screening to all districts, the OASIS system helps to ensure that problem products will be recognized as such at whatever port they enter. The review criteria can be revised within minutes to respond to emerging problems. The OASIS system accomplishes in minutes what used to take days.

IV. ENHANCEMENTS UNDERWAY TO THE CURRENT IMPORT PROGRAM

FDA currently is updating OASIS to make it a more efficient and effective tool. We are enhancing the system to link various Agency databases to OASIS, which will allow inspectors easy access to additional Agency databases (such as Import Alerts and Low-Acid Canned Food registrations) that might have risk information relevant to the decision about how a particular shipment should be handled. This improvement to the existing system will reduce the amount of time needed to determine what action to take on individual entries and is expected to be operational by the end of the year.

The Agency also has safeguards against importers who continue to submit erroneous entry data. As part of FDA's implementation of the OASIS system, FDA conducts evaluations of all filers, and strives to evaluate every filer once a year. FDA randomly selects entries of a given filer that were designated as "May Proceed" and requests that the filer provide the paper documentation for these entries. The information on the paper documentation is compared to the electronic documentation for accuracy and consistency. When a filer is identified with an error rate in excess of 10 percent and the errors do not appear to be deliberate, FDA will work with the filer to

correct the problem. This effort could include providing guidance on how to submit their data correctly, or simply taking greater care to avoid typographical errors. If the filer still cannot achieve an error rate of 10 percent or less, the filer will be required to submit paper documentation for every entry until their error rate is reduced to an acceptable rate. If the pattern of errors indicates deliberate submission of erroneous data in order to facilitate entry of violative food, the filer must immediately submit paper documents for all entries, and FDA may refer the matter for criminal investigation. As of August 1998, out of 2,293 electronic filers, 1,315 were evaluated within a nine month period and 247 were found to have an error rate in excess of 10 percent. Of the 247 filers with an error rate in excess of 10 percent, only one was removed from electronic status after efforts were made to assist the filers in making corrections to reduce their error rate.

Since implementation of the OASIS system began in all districts in 1997, FDA has been working with the filers to help them learn the system in order to submit correct data consistently. FDA continues to conduct product code training and other types of data entry training around the country. We believe this has been an appropriate approach in light of the recent implementation and complexity of the system.

V. THE TWO PRESIDENTIAL FOOD SAFETY INITIATIVES

As the Committee is well aware, improving the overall safety of food has been a focus of the Clinton Administration. In the past 16 months, the Administration has announced two major

initiatives to improve the safety of the food supply. The first is the President's May 1997 National Food Safety Initiative, a multi-agency approach involving FDA, the Centers for Disease Control and Prevention (CDC), the U. S. Department of Agriculture (USDA), and the Environmental Protection Agency to reduce the incidence of foodborne illnesses by enhancing the safety of both domestic and imported foods. Some of the measures being implemented include an expanded early warning surveillance system for foodborne illnesses, strengthened communication between State and Federal agencies to coordinate the response to foodborne disease outbreaks, education campaigns directed at consumers and retail food service establishments to improve food handling practices, focused research on better risk assessment techniques for foodborne pathogens, and research to develop new methods to detect and prevent foodborne pathogens. This initiative is described in greater detail in *Food Safety From Farm To Table: A National Food-Safety Initiative, A Report to the President, May 1997.*

In addition, in October 1997, President Clinton issued a two-part directive specifically to improve the safety of imported and domestic fresh produce. The first part was a directive to the Secretary of Health and Human Services and the Secretary of Agriculture to work together and in close cooperation with the agricultural community to develop voluntary guidance, regarding good agricultural practices and good manufacturing practices (GAPs and GMPs). The voluntary guidance targeted towards both the domestic and foreign industry recommends various approaches to reduce the risk of microbial contamination of fresh produce throughout the production and distribution system. We have received a great deal of public input and worked with the states on this guidance and are revising the guidance based on this input. We expect to

publish the final voluntary guidance in early October 1998.

The second part of the produce initiative is legislation aimed at ensuring imported foods are as safe as domestic foods. Because this legislation directly addresses one of the recommendations in the GAO report, I will defer my remarks on this topic until after I discuss the report.

VI. ADDITIONAL RESOURCES REQUESTED BY THE ADMINISTRATION

The Administration also has sought additional funding to implement these initiatives. With strong support from the Congress, we received the first installment for the President's Food Safety Initiative in FY 1998 of $24 million, the full increase for food safety sought by the Administration that year for FDA. This funding has allowed us to lay a foundation for improving the safety of foods through implementation of Hazard Analysis Critical Control Points (HACCP) in the seafood industry, as well as develop activities in the areas of surveillance, research, risk assessment, coordinating more response to food borne outbreaks at the federal, state, and local levels, and education. We are proud of a number of significant accomplishments that have already occurred with this funding. For example, we are using FoodNet and PulseNet data to identify and contain more quickly outbreaks before large numbers of people become ill. We have developed new and improved methods for detection of pathogens, such as Cyclosporasis. Educational efforts are changing consumers' unsafe food practices; surveys indicate that fewer consumers are eating raw oysters, improperly cooked eggs, and rare hamburger. The interagency Risk Assessment Consortium has been formed as a forum for the development and use of uniform and

consistent approaches to risk assessment in food safety. These are only a few of the accomplishments made possible by the President's Initiatives.

For FY 1999, the Administration is requesting $101 million for the Food Safety Initiative. Our FY 1999 request builds upon this foundation by targeting the areas of imports and produce. Of the Administration's total request, $50 million is for FDA. Of this amount, $25 million would be devoted toward activities to improve the safety of imports. This funding would be used not only to put additional inspectors at the borders, but also to take a very proactive approach to imports by evaluating the food production systems of other countries wishing to export to the U.S. With this funding, our goals are to conduct such activities as these overseas evaluations, provide educational outreach and technical assistance to promote use of GAPs, promote use of Mutual Recognition Agreements and other agreements, increase the accuracy of import entry data, and increase sampling of high risk food at the border.

VII. THE GAO REPORT

While FDA is implementing important measures to improve the safety of food imports, additional improvements must be made. In this regard, the April 1998 GAO Report makes several observations and recommendations. The Report's recommendations fall into three main areas:

- First, the Report recommends that Congress require that all foods imported into the U.S. be produced under equivalent food safety systems. USDA already has such authority to control imported meat and poultry products in this manner.

- Second, GAO recommends several improvements to more effectively target resources on high risk imported foods. These improvements include altering our work plan to provide better guidance to our inspectors, enabling our inspectors to access all health risk databases from OASIS, and ensuring that importers submit accurate data into our electronic entry system.
- Third, the Report recommends that FDA improve its control over food imports prior to a decision that such food may proceed in domestic commerce. These improvements include re-evaluating the use of private laboratory tests by importers, retaining better control over questionable products, marking refused items, and imposing stiffer penalties for those who ship unsafe products.

We agree with many of GAO's findings and recommendations and would like to address them in turn.

VIII. AUTHORITY TO REQUIRE THAT FOOD IMPORTS ARE PRODUCED UNDER A SYSTEM THAT MEETS THE U.S. LEVEL OF PROTECTION

I first would like to address the recommendation that FDA be given statutory authority that would enable us to ensure that products imported into the United States have been produced under a system that provides the same protection as domestically produced foods. As I have stated previously, there is no doubt our current system to protect Americans against unsafe imported products is in need of revision. We simply cannot rely solely on catching problems at the border

through inspection. The GAO Report has made this a priority and devoted a substantial portion of the report to this recommendation.

The issue of FDA's support of this proposed authority was questioned at the May 14 hearing. We fully endorse this recommendation, and the Administration has requested legislation to give FDA explicit statutory authority to require that all imported foods are produced under a system that meets the level of protection applicable to domestic foods. FDA's only concern has been over GAO's use of the word "equivalent". This concern arises because the term "equivalent" has a particular meaning in the context of the World Trade Organization's SPS agreement; it has been interpreted by some of our trading partners to always require formal agreements. These agreements involve a lengthy and resource intensive process, which, in our view, should not be required as part of the statutory authorities that GAO has recommended.

As you know, S. 1707, introduced by Senators Barbara Mikulski and Ted Kennedy, (and its companion bill H.R. 3052 introduced by Representatives Anna Eshoo and Frank Pallone) would add a new provision to section 402 of the Act that would deem imported foods to be adulterated if the Secretary (and by delegation FDA) determines that the imported products were not prepared, packed, or held under a system or subject to conditions that either meet the requirements of our Act or "otherwise achieve the level of protection" required by our Act for domestic foods. In making that determination, the Secretary could consider whether the country, firm, or establishment has allowed FDA access (including sample collection) upon our request.

This legislation puts the emphasis on underlying systems of control at their source rather than finding contaminated food shipments at our border or, worse yet, after people get sick. In other words, it is a move from reaction to prevention. If enacted, this legislation would achieve a better allocation of FDA resources by taking into account the production, processing, and handling of food products rather than only focussing on products when they are offered for import, a focus we can no longer afford to rely on solely given the dramatic rise in imported foods and our current level of resources. This legislation is consistent not only with GAO's recommendation, but also with the August 1998 IOM/NRC Report.

Let me make one other point. FDA plans to undertake the activities identified in the President's Food Safety Initiative and Produce Initiative. While enactment of this legislation would enhance our ability to improve the safety of imported foods, in the absence of such legislative authority, we can, and if the additional funds that have been requested are provided, still move ahead to meet each of the goals listed previously

IX. TARGETING RESOURCES ON HIGH RISK IMPORTED FOODS

While there is no doubt we must begin to focus on prevention, we cannot ignore the continued importance of inspection at the border. The GAO Report made several recommendations involving the Agency's ability to target our inspectional resources on high risk imported food products. We agree that, given current resources, we must focus on those entries that pose the greatest threat to public health. As I have mentioned, FDA already has been taking many of the

steps recommended by GAO. More specifically, the Agency has been and will continue to work to link the OASIS system to other databases, as well as our efforts to work with filers to prevent the entry of errors into the electronic entry system. In addition, we are reviewing the tools we use to assist field staff in prioritizing their work.

FDA supplies guidance to its field staff to target their work. The primary mechanisms for doing this are Compliance Programs, Assignments, and Import Alerts and Bulletins. Compliance Programs reflect Agency priorities based on anticipated risk associated with a product and list individual products and the problems that can be associated with those products, as well as countries and or regions from which samples could be collected. They also contain other guidance based on FDA's past accomplishments and surveillance information to guide the field force in selecting imported products to sample. Assignments, containing information similar to that in Compliance Programs, usually are issued to gather information on new or emerging problems. Import Alerts and Bulletins identify known or potential problem foods (by country and manufacturer) and contain guidance to our field offices as to appropriate actions.

FDA's Workplan, on the other hand, is a management tool used to assign the number of operations (field examinations, sample collections and analysis) that the Agency will perform on a national basis. Each district then is assigned its proportionate share of operations to perform during the year. The Workplan reflects the Agency priorities contained in Compliance Programs, but is not the only reflection of overall Agency import priorities. The GAO report noted that FDA did not meet the goals set forth in the Workplan, principally because the Workplan did not

factor in the time required to investigate emergencies and consumer complaints. FDA does not disagree. Consequently, we have established an internal working group of both field and headquarters personnel to examine how to factor in emergencies and consumer complaints in order to better plan import work and report activities. We hope to implement recommendations from this group in FY 1999.

X. IMPROVING CONTROL OVER IMPORTED FOODS PRIOR TO RELEASE BY FDA

GAO also recommended that FDA improve its control over imported foods prior to a decision by the Agency that the goods be allowed to enter into domestic commerce. I would like to respond to this category of recommendations by highlighting controls that FDA is currently considering, some of which can be achieved administratively.

A. Independent Laboratories

FDA generally agrees with GAO's observation that FDA needs to exercise better control when permitting importers of foods subject to detention without physical examination to select a laboratory to analyze their products, to certify that the labs sampled the product once, and that the information provided is true and correct. To this end, we plan to revise our internal laboratory procedures manual to offer additional guidance for our district offices regarding the submission by private laboratories to FDA of analytical packages in post-detention sampling.

B. Improved Cargo Control

The GAO Report criticized the Agency for allowing the importer to retain control over imports and GAO observed problems such as substitution of cargo and failure to redeliver the goods after FDA has refused admission. This is a serious criticism, and FDA agrees that better controls over incoming cargo are necessary. We are evaluating new ways to require importers to securely hold articles identified for detention without physical examination. One option would be requiring that the goods be held in a bonded warehouse, at the importer's expense, until FDA makes a final entry decision. Certain exemptions from any new requirement may apply in some instances, such as if the Agency has an agreement with the country of origin establishing that the foreign food safety system meets our level of protection or if the articles are highly perishable.

C. Marking Refused Goods

An additional control tool would be to require that such products be marked "refused" or "refused admission" if the articles were rejected under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act (PHS Act), or the applicable regulations. FDA currently does not have explicit authority to mark goods or to require the marking of goods refused entry. Consistent with the observations made by GAO in the April report, as well as at the September 10 hearing, however, the Agency is considering a regulation based upon its implicit authority in the FD&C Act and the PHS Act. Such a regulation could require the marking of refused goods to aid the Agency in identifying these products should the importer attempt to reenter them without reconditioning.

D. Partnership with U.S. Customs Service

An additional theme throughout this section of the GAO report is FDA's relationship with USCS. We believe that this is a close, cooperative relationship as shown by our cooperation in investigating criminal activities; our joint efforts in linking OASIS with the USCS system; and, our daily contacts in monitoring imports at the over 330 ports-of-entry where FDA-regulated products enter the U.S. But like any relationship, there always is room for improvement. USCS and FDA already have established a working group to explore the issue of cargo control and a second working group to develop mechanisms to improve the sharing of valuable information. The efforts of these two groups will hopefully enhance the partnership we have with USCS.

XI. IMPROVING FDA'S ABILITY TO TRACE BACK FOOD PRODUCTS TO THE SOURCE OF PRODUCTION

Although the GAO Report did not address our ability to trace food products back to their production source, the Agency believes such ability can be a key element of public health protection. For that reason, I would like to address this issue.

FDA and the food industry share an interest in improving the ability to trace back and to identify the source of foods that pose health hazards to the American public, including fresh produce. For FDA (and CDC), a trace back to the source of production allows us to conduct more thorough investigations more quickly (before evidence gets lost or spoils). For industry, more precise identification of the source of production can reduce instances where consumers believe an entire

category of products is unsafe, when the problem is associated with the products of just one or a small number of manufacturers, distributors, or growers.

Because of our shared interest in utilizing a trace back, FDA and industry have had a number of discussions about steps that industry could take to improve traceability. For packaged food, a trace back can usually be established because food packages or labels are required to include information that allows FDA to trace the foods at least to the distributing firm. Fresh produce presents a very different situation. Many small producers are involved, and when their products enter our country's vast and complex distribution system, the information that links a farm to the product in the supermarket display case can easily be lost. Product marking seems to be a more pragmatic approach than requiring detailed distribution records, but even product marking is a complex issue for products typically sold in bulk, products commingled with products from other sources, and products sold to the consumer unpackaged. Industry is increasing its use of stickers or tags, and our investigators have found some of the bar codes being used on certain wrapped produce an especially efficient source of information, but these practices are not yet widespread or economically efficient.

FDA will continue to discuss this issue with the industry. At this time, we see many practical problems to imposing a trace back requirement. We are quite hopeful that the industry's keen interest in finding workable solutions will lead to enhanced product marking practices.

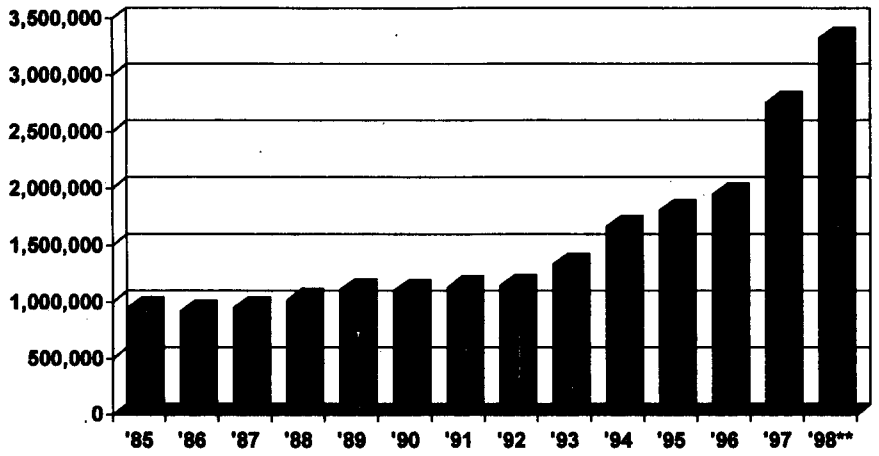
XII. CONCLUSION

Madam Chairman and Members of the Committee, FDA is serious about significant reforms of its import program. But we believe that neither the current approach nor the current level of resources to handle the increasing quantities of foods that are being imported into this country are sufficient. Instead, as both the President and GAO have recognized, we must change our approach. Rather than relying solely on inspections at the border, we must place a greater emphasis on the regulatory systems of the foreign countries that are exporting to us. In addition, without a significant increase in resources, as requested in the President's FY 1999 budget, a strong import program is not possible.

We appreciate and welcome the Committee's interest in this important subject, and we look forward to working with the Committee to find ways to improve the Agency's imported food program.

My colleagues and I would be pleased to answer any questions. Thank you.

FDA Food Imports*



*Quantities represent line items of food offered for import
**estimated

Testimony of
Sanford A. Miller, PhD and Harley W. Moon, DVM, PhD
Representing
Committee to Ensure Safe Food From Production to Consumption
Institute of Medicine/National Research Council
September 24, 1998

Good morning, Senator Collins and members of the Senate Permanent Subcommittee on Investigations. We are Sanford Miller and Harley Moon. We both served as members of the Committee to Ensure Safe Food from Production to Consumption of the National Academy of Sciences (NAS), Institute of Medicine (IOM), and National Research Council (NRC). Dr. Miller is Dean of the Graduate School of Biomedical Sciences at the University of Texas Health Science Center at San Antonio. He is the former Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. Dr. Moon is the F.K. Ramsey Chair of Veterinary Medicine at Iowa State University. He is the former director of the Plum Island and National Animal Disease Centers at the Agricultural Research Service.

The NAS is a private, nonprofit society that was chartered by Congress in 1863 to advise the government on scientific and technical matters. The IOM was established by the NAS to examine policy matters pertaining to the health of the public. The NRC is the operating arm of the NAS, NAE, and IOM.

Let us briefly describe how we work, because it is important for an understanding of the value of our recommendations. The Academy and the IOM differ from most other academies of science and medicine in the world in that they are not just an honorific body. From the outset, it was intended that they provide independent advice to the government on matters of science, medicine, and technology. We do so through the National Research Council and the IOM, using thousands of experts from academe, industry, and other organizations who volunteer their time. During any given year more than 6,000 scientists, engineers, and health professionals participate in our activities, most of them at the request of the federal government. We actively strive for a balance of views among our committee members and subject them to a conflict of interest review.

Our usual product is an independent consensus report. From initial approval of a study to this final report, every project is subject to oversight by supervisory boards and commissions within the NRC and IOM whose members are, again, volunteer experts--often members of the Academies. The final step in our rigorous quality-control process is a review by outside anonymous experts who did not serve on the study committee. The sponsoring federal agencies have no role in the process and do not see a report until it is ready for public release. The study that we will address today was requested by Congress and was supported by the U.S. Department of Agriculture's Agricultural Research Service.

1. What deficiencies, if any, in the current food import process did your Committee identify or include in the final report?

The globalization of the US food system brings foods from all parts of the world into the US marketplace, and with it the potential for foodborne infection or other hazards not normally found in the United States. The production, processing, and shipment of

food produced in the United States can, in theory, be subject to government monitoring from field harvest to consumer purchase, but imported food is not subject to similar oversight.

The committee reported that protecting the safety of domestically produced food is a daunting challenge, but the country's growing reliance on imported food adds additional layers of complexity. It is by no means clear that imported food, as a class, poses greater risks than does domestically produced food. What is clear is that federal officials cannot use the same methods to regulate imported food that they use—or that would make sense—in regulating domestically produced food. Methods that rely on production-site monitoring of compliance with safety standards or universal physical inspection of marketed shipments cannot be directly translated overseas.

Theoretically, Congress could forbid the importation not only of food that does not meet all domestic standards but also of food whose production is not subject to oversight by US officials in the same fashion as if it were produced domestically. Such a policy would require exporting countries to allow regular inspections by US inspectors; this would be politically unlikely and very expensive. Accordingly, the United States has adopted different strategies for protecting the safety of imported food.

The laws that FSIS and FDA administer require that imported food meet the same standards as domestic food. But, as the subcommittee is aware, the enforcement approaches of the two agencies to meet this common requirement are quite different. The different systems of scrutiny of imports used by FDA and USDA largely mirror their different approaches to domestically produced food as is required since they must document domestic equivalence. USDA statutory authority requires meat and poultry food safety systems of exporting countries to be equivalent to the US system.

However, FDA lacks the authority to require that imported foods be produced under a system equivalent to the one that it administers domestically; instead, FDA relies primarily on sampling at ports-of-entry to determine whether food imports meet domestic requirements. Even if FDA's criteria for sampling and testing were systematically risk-based and its resources were adequate to keep up with an increasing volume due to increased demand, sample analysis is not capable of detecting many of the most serious risks to consumer health. The major outbreak of foodborne illness traced to raspberries from Guatemala could not have been prevented by port-of-entry inspection, even if an inspection had taken place.

In fact, although both agencies have computerized systems to assist in inspection and tracking, there is no way to determine whether the agencies are focusing their attention on the most important health risks. Both agencies target resources to meet the problems of past violations, in which contamination, processing defects, labeling, and quality were at issue.

The General Accounting Office has reported that FDA lacks the necessary controls over detained and suspect shipments. Unscrupulous importers are able to circumvent the system, and are seldom punished in proportion to the seriousness of their violations.

Similar concerns center on fish and shellfish inspection as over 50 percent of the fish and shellfish consumed in the United Sates is imported. Personal communication to the committee from the Centers for Disease Control and Prevention in June 1998 found that shellfish alone caused 21 percent of all reported foodborne illnesses from 1978 to 1992.

In an effort to address the challenges of ensuring the safety of imported foods, the President has proposed a variety of measures including hiring additional FDA inspectors

to examine the safety of fruits and vegetables in the marketplace, both domestic and imported. In addition, legislation is being proposed to allow FDA to halt imports of fruits, vegetables, and other food products that do not meet US food safety requirements or that do not provide the same level of protection as is required for US products. Recognizing that sample analysis does not provide a means for detecting many of the most serious risks to consumer health, and without firm knowledge of most significant risks, it is impossible to know whether these proposed actions will adequately address imported food hazards.

2. What recommendations were offered by your Committee to establish an effective food safety system in the August 20th NAS report?

The report "Ensuring Safe Food From Production to Consumption" came to three primary conclusions:

I. An effective and efficient food safety system must be based in science.

II. To achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised.

III. To implement a science-based system, reorganization of federal food safety efforts is required.

To accomplish these objectives, the report recommends that the following measures be taken regarding the scientific and organizational changes needed to improve the US food safety system:

Recommendation I: Base the food safety system on science.

The United States has enjoyed notable successes in improving food safety. One example is the joint government-industry development of low-acid canned food regulations, based on contingency microbiology and food engineering principles, that has almost eliminated botulism resulting from improperly processed commercial food. Similarly, the passage of the 1958 Food Additives Amendment to the Food, Drug, and Cosmetic Act of 1938 was a "technology forcing" event that improved the evaluation of the safety of added and natural substances and reduced the risks associated with the use of food additives. In a like manner, the Delaney clause of that amendment resulted in increased attention to carcinogenic substances in the food supply. With increasing knowledge, many rational, science-based regulatory philosophies have been adopted, some of which rely on quantitative risk assessment. Adoption of such a science-based regulatory philosophy has been uneven and difficult to ensure given the fragmentation of food safety activities, and the differing missions of the various agencies responsible for specific components of food safety. This philosophy must be integrated into all aspects of the food safety system, from federal to state and local.

Recommendation IIa: Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

Limitations on the resources available to address food safety issues require that food safety activities operate with maximal efficiency within these limits. This does not require full-scale, cost-benefit analysis of each issue, but it does require that costs, risks, and benefits be known with some precision. Thus, where feasible, regulatory priorities should be based on risk analysis which includes evaluation of prevention strategies where possible. The greatest strides in ensuring food safety from production to consumption can be made through a science-based system that ensures that surveillance, regulatory, and research resources are allocated to maximize effectiveness. This will require identification of the greatest public health needs through surveillance and risk analysis, and evaluation of prevention strategies. The state of knowledge and technology defines what is achievable through the application of current science. Public resources can have the greatest favorable effect on public health if they are allocated in accordance with the combined analysis of risk assessment and technical feasibility. However, limiting allocation of resources to *only* those areas where high priority hazards are known can create a significant problem: other hazards with somewhat lower priority but with a much greater probability of reduction or elimination might not be addressed due to limited resources. Thus both the marginal risks and marginal benefits must also be considered in allocating resources.

Not all agencies responsible for monitoring the safety of imported food are authorized to enter into agreements with the governments of exporting countries in order to reciprocally recognize food safety standards or inspection results. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance, and inspection activities within other countries. This should permit inspection and monitoring efforts to be allocated in accordance with science-based assessments of risk and benefit. Changes in federal statute that would foster and enhance science-based strategies are:

- Eliminate continuous inspection system for meat and poultry and replace with a science-based approach which is capable of detecting hazards of concern;
- mandate a single set of science-based inspection regulations for all foods; and
- mandate that all imported foods come from only countries with food safety standards deemed equivalent to US standards.

Recommendation IIb: Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit.

Changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food. Such a plan, as shown below, should serve as the blueprint for strategies designed

to determine priorities for funding, to determine what the needs are, and to ensure that they are incorporated into activities and outcome evaluation.

The National Food Safety Plan should:

- Include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
  - — monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
  - — improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

Recommendation IIIa: To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

The report indicates that the current fragmented regulatory structure is not well-equipped to meet the current challenges. The key organizational recommendation is that in order for there to be a successful structure, one official should be responsible for federal efforts in food safety and have control of resources allocated to food safety. This recommendation envisions an identifiable, high-ranking, presidentially- appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food safety effort; the structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives. It is also important that the person heading the structure should be accountable to an official no lower than a cabinet secretary and, ultimately, to the President.

Many members of the committee were of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. However, designing the precise structure and assessing the associated costs involved were not possible in the time frame given the committee, nor

were they included in its charge. The committee did discuss other possible structures; while it ruled out some, it certainly did not examine all possible configurations.

The committee did not believe that the type of centralized focus envisioned can be achieved through appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based 'czar'. Nor, in the committee's view, can this goal be achieved through a coordinating committee similar to that currently provided via the National Food Safety Initiative. In evaluating possible structures, the committee realized that past experience with other structures or reorganizations, including the creation of new agencies, such as the Environmental Protection Agency (EPA), should inform any final judgment. Further, it is quite possible that other models may now exist in government that can serve as templates for structural reform. Whether or not a single agency emerges, the ultimate structure must provide for not just delegated responsibility, but also for control of resources and authority over food safety activities in the federal government.

Recommendation IIIb: Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

The report specifically addresses the federal role in the food safety system, but the roles of state and local government entities are equally critical. For integrated operation of a food safety system, officials at all levels of government must work together in support of common goals of a science-based system. The federal government must be able to ensure nationwide adherence to minimal standards when it is deemed appropriate. The work of the states and localities in support of the federal mission deserves improved formal recognition and appropriate financial support. Statutory tools required to integrate state and local activities regarding food safety into an effective national system include:

- Authority to mandate adherence to minimal federal standards for products or processes,
- continued authority to deputize state and local officials to serve as enforcers of federal law,
- funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance the safety of food,
- authority given to the federal official responsible for food safety to direct action by other agencies with assessment and monitoring capabilities, and
- authority to convene working groups, create partnerships, and direct other forms and means of collaboration to achieve integrated protection of the food supply.

The report recognizes that the above recommendations will need significant review and discussion. The committee focused on the need for a centrally managed federal system to ensure coordination and direction in food safety programs and policy, and to serve as a single voice with authority and resources to suggest and implement legislation. It had insufficient time to review all the possible organizational structures that could accomplish this goal. Of critical importance, though, are the first two recommendations: the first, to base the system on science, and the second, that of rewriting the current patchwork of federal food statutes that in many cases do not serve to ensure a

scientifically supportable and risk-based food safety system, and certainly prevent it from being more cost effective.

Regardless of the organizational structure chosen, a revamped federal food statute is critical to being able to reallocate resources toward risks that have or will have the greatest significance to the public's health. Implementation of these recommendations should not be looked at as a cost-cutting measure, but rather as a way to design a well-defined integrated system to ensure safe food. This system may well be able to demonstrate effectively a need for additional resources to address important and specific problems. Although the National Food Safety Initiative properly seeks to alleviate problems inherent in the present decentralized structure, experience indicates that any ad hoc administrative adjustments and commitments to coordination will not suffice to bring about the vast cultural changes and collaborative efforts needed to create an integrated system.

Changing hazards associated with food and changing degrees of acceptance of risk are factors that impact the nation's ability to protect public health and ensure safe food. Risk acceptance and foodborne hazards will continue to change and evolve with new technologies and consumer demands. Federal food safety efforts must be designed to deal with those changes. The report is not a comprehensive and all-inclusive discussion of these issues. Adoption of the recommendations in the report will not end the effort to make food safer. They should, however, contribute to ensuring the safety of our food while providing a blueprint for a truly integrated system.

3. How does the President's Executive Order establishing a food safety council compare with the options contained in the August 20th report.

Since the Committee to Ensure Safe Food from Production to Consumption ended its deliberations with the publication of the August 20th report, it cannot comment on the President's Executive Order which established a food safety council and was announced August 25, 1998. It is important to note, however, that the report did not provide "options" for specific consideration; it provided a few of potentially many examples of organizational structures that might be in concert with the criteria outlined in the report. However, the committee believed that the type of centralized focus necessary for an integrated and effective national food safety system could not be achieved through the appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based 'czar'. Nor, in the committee's view, could the goal be achieved through a coordinating committee similar to that in place via the National Food Safety Initiative.

4. How can scientifically supportable assessments of risk to public health be used to create more effective safeguards to protect the public from foodborne threats? Can resources be better allocated if regulatory decisions are based on scientifically developed data?

The report discusses that decisions need to be based on assessments of risk to public health, and that resources should be allocated toward those that indicate greatest risk to health. However, the report also recognizes that great gaps exist in information needed upon which to base some of these assessments, in which case judgments made need to be

based on whatever scientific data is available. In many cases, resources targeted toward risks of lower priority may be of significant benefit to decreasing risk. In that case, some areas may need to be provided resources even though there may be areas that pose greater risk to public health, but for which additional resource allocation would have little likelihood of more effectively protecting the public.

In summary, the committee's recommendations focus on the need for a science-based, centrally managed federal system to ensure coordination and direction in food safety programs and policy, and to serve as a single voice with authority and resources to suggest and implement legislation. The concerns related to importation deal with both the existing differences in authority to regulate imports among agencies, and premise that science-based risk analysis be used as the basis upon inspection and regulation of all imported food products occur regardless of category. With regard to organizational structures that could serve to better implement the regulatory changes recommended, the committee proposes that a sequential, detailed examination of specific organizational changes be a major component of future study, in keeping with the Congressional appropriations language which requested this evaluation.

Statement of

TIM HAMMONDS, PRESIDENT AND CEO
FOOD MARKETING INSTITUTE

Before the

SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

Hearing on

IMPROVING THE SAFETY OF FOOD IMPORTS
September 25th, 1998

Good morning Madam Chairwoman and members of the Subcommittee. I am Tim Hammonds, President and CEO of the Food Marketing Institute (FMI). I am honored to have the opportunity to testify before you today.

Let me start by commending you and your Subcommittee for investigating the adequacy of government programs to ensure that imported foods are safe. Your inquiry is needed. It is overdue. FMI wants to work closely with you to ensure the safety of all food, both domestic and imported, that we sell to our customers.

FMI is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries — food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion — more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets.

As an industry, America's food retailers and wholesalers are committed to the safety, quality and affordability of food products for consumers, and FMI's members are leading the way. Supermarkets are the primary points where customers interact with the food industry. Consequently, we are vitally concerned about public policies that affect our ability and commitment to provide safe and wholesome food.

Consumer confidence is critical. Producers, manufacturers, government, and especially retailers, all have a vested interest in maintaining the highest level of confidence. Consumers today are highly concerned about food safety, according to FMI's 1998 *Trends in the United States — Consumer Attitudes and the Supermarket*, but they still have a strong overall level of faith in the food supply. I am very pleased to tell you that

only 6 percent of those sampled in our national survey believe that food safety problems are most likely to occur in supermarkets. Only farmers have a marginally higher degree of public credibility on food safety issues than do supermarkets.[1]

Critical to maintaining this level of confidence is to continue providing consumers with credible food safety information. This was identified in the 1997 report to the President titled *Food Safety From Farm to Table: A National Food Safety Initiative*. Also last year, Secretaries Glickman, Riley and Shalala, in a Memorandum of Understanding, formalized a food safety education partnership that includes FMI, other industry partners, consumer groups, and the U.S. Departments of Agriculture, Education, and Health and Human Services. Together, we have launched a far-reaching, ambitious, nationwide campaign, titled Fight BAC!™. Our goal is to educate consumers on the four simple steps they can take to reduce their risk of foodborne illness.

Moreover, FMI strives to ensure that retail store operators and their associates are meeting their responsibility to maintain the safety of food. Hundreds of retail employees are given instruction each year in how to properly handle various foods in a grocery store setting. FMI has created a Food Handler Certification program for the industry that recognizes retail employees who successfully complete a rigid food safety curriculum and pass a food handler's examination.

FMI recently launched a comprehensive initiative called Total Food Safety Management. We are developing, along with our retail members, a HACCP-based program for maintaining food safety in retail stores for products that have the highest risk for causing illness. In cooperation with IDEXX Laboratories, Inc., a Westbrook, Maine-based company, we are developing models for safe food handling. Each model is being pilot-tested in a real-world setting to confirm its effectiveness and practicality. These models will then be incorporated into our training materials and be made available to all retailers.

There is widespread scientific consensus that foodborne illness is a growing public health problem. At the same time, consumers today are listening to the advice of health experts, who agree that Americans should be eating more fruits and vegetables. The U.S. Department of Agriculture, Food and Drug Administration, American Cancer Society, American Heart Association and others are encouraging consumers to improve their diet by eating more fresh produce. As a result, fresh produce consumption rose 27 percent from 1970 to 1993, and continues to increase.

This increase means that consumers have become more demanding and expect supermarkets to provide a wide variety of fresh fruits and vegetables year-round. The produce department is now the most important selling area in a supermarket. It is currently estimated that grocery stores account for over $43 billion of the $64 billion in annual fresh produce sales in the United States.

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[1] Four percent of the public feel that food safety problems are most likely to occur at the farm, according to FMI's 1998 *Trends in the United States — Consumer Attitudes and the Supermarket*, which is based on a survey of more than 2000 shoppers.

The average produce department carries more than 340 items year-round. However, it is in large part because the industry has access to imports that we are able to put certain foods, such as tomatoes, on our shelves at times of the year when they cannot be grown in the United States, or offer our customers more exotic foods that are not, or cannot be, produced domestically. The global agricultural market makes this abundance of choices possible. FMI believes that this abundance makes "eating healthy/smart" more enjoyable and, therefore, consumers are be more likely to do so.

Yet even as Americans are eating more fresh produce, they are also hearing about risks they might face from foodborne health hazards such as *E. coli* O157:H7, Hepatitis A, *Salmonella* and *Cyclospora*. To the average consumer, all these messages must have a confusing and often frightening effect. Consumers rely upon their grocers and their government to ensure that their food is safe. They assume that the food supply is generally safe and trust that the government has mechanisms in place to keep unsafe food out of our country. In fact, according to a survey by *Produce Merchandising*, when shopping for fresh produce, Americans are not concerned about which country their produce comes from, but look rather for freshness, quality and price. In other words, they expect all the foods they buy to be safe.

As the point where consumers and the food distribution system meet, America's grocers face a daily challenge to give their shoppers the variety of foods they desire, while ensuring that those foods are as safe as possible. In rising to this task, FMI members take extreme care to maintain the quality and safety of the foods that come into their stores. However, grocers must also rely on the individuals who produce and deliver products to their stores to maintain the safety of those food items. Retailers cannot reverse the processes of nature and make unsafe food safe again.

Food retailers, like their customers, also rely on the government to fulfill its role as overseer of the safety of all foods. Consequently, FMI continues to strongly support an efficient and effective federal food safety oversight system. We believe this oversight system should be based on sound science and risk analysis with its primary emphasis placed on preventing contamination at its source. We also believe strongly that sufficient resources should be allocated to implement comprehensive programs.

American consumers must be able to have confidence in the nation's food supply. But as this series of hearings has made apparent, our current system for federal oversight of imported fruits and vegetables is certainly not efficient and sometimes not effective. In the first hearing, the public learned about inadequacies at our ports of entry, ranging from jurisdictional conflicts to computer systems that do not work. The General Accounting Office, in its report titled *Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, also noted that the Food and Drug Administration and the Customs Service have "had problems stopping importers from distributing unsafe foods under FDA's jurisdiction."

At subsequent hearings, we became familiar with the tricks of unscrupulous importers, such as bribery and "port shopping." These revelations do not sit well with consumers

and certainly not with grocers, who rely upon government agencies to stop unsafe food at our borders. FMI strongly urges that steps be taken to address these problems.

As Congress and the Administration move forward to improve government oversight of our nation's food production and distribution systems, I caution against adopting policies that will serve as anticompetitive barriers to free trade or unfairly restrict the consumer access to imported foods. Domestic producers are not helped by such restrictions since consumers, when made aware of a health hazard associated with a particular food, tend to avoid purchasing that food, whether it was produced domestically or abroad.

In developing the reforms needed to improve the safety of produce, FMI recommends that Congress consider the proposals put forth in the President's Food Safety Initiative and in the National Academy of Sciences (NAS) report titled *Ensuring Safe Food from Production to Consumption*. These proposals provide an excellent foundation and framework for the reforms needed.

Develop a Better System

NAS recommends that food safety programs be based on risk analysis, focus on the prevention of contamination, and employ monitoring systems to provide for ongoing safety analysis. The President's initiative supports programs like FSIS's pathogen-reduction and HACCP systems, which focus on prevention and compliance with performance standards. A program to improve the safety of imported produce could include the following components:

A system to evaluate the food safety programs of foreign countries that export produce to the United States to ensure equivalency with U.S. standards.

Federal authority to reject produce shipments based on the exporting country's food safety management procedures as documented by the agency with regulatory authority.

A system to monitor imports into the United States similar to FSIS's port-of-entry program.

Food safety standards based on scientific data that can be employed at the point of inspection.

A monitoring and verification system to measure performance, based on the risk to consumers, against the established standards using systems such as the FSIS microbial baseline data for meat and poultry, the FSIS Automated Import Inspection System (AIIS) and the FDA Operational and Administrative System for Import Support (OASIS).

Improved coordination between FDA and the U.S. Customs Service.

Improve Use of Resources

Regardless of the exact nature of the system redesigned to improve the safety of imported food products, one critical resource need must be addressed. Sufficient personnel will be necessary for inspection and monitoring at ports of entry. In its report, NAS concluded that "FDA's lack of resources to maintain adequate inspection and monitoring of...fresh fruits and vegetables, both domestic and imported, using statute-driven methods of monitoring and enforcement, increases the threat of foodborne disease and related hazards in the food supply." FDA itself has acknowledged that it does not have adequate resources or the authority to develop an effective food safety program for imported produce.

FMI believes this critical need for additional personnel can be met by redeploying to ports of entry existing USDA/FSIS in-plant inspectors freed from their current duties by the modern HAACP-based inspection system for meat and poultry.

There is no question that these personnel will be available for redeployment. In July of this year, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) published a background document on "HACCP-Based Inspection Models." In this document, FSIS proposes a new meat and poultry inspection model that will "reduce its reliance on organoleptic (sight, smell and touch) inspection, shift to prevention-oriented systems based on public health risk, and redeploy its resources in a manner that better protects the public from foodborne illness."

When this new HACCP-based inspection system is in place, FSIS will no longer need its current complement of inspectors, freeing up thousands of staff-hours for use in other areas of food safety. Indeed, earlier this year FSIS announced its strategic plan to redeploy those resources. FSIS also proposed to "put a flexible structure in place that can accommodate new or changing tasks," but it has not evaluated risks throughout the food distribution system to properly determine where these resources might be most effectively used to prevent contaminated foods from reaching the consumer. These hearings have identified precisely where those resources would be most effective — at our ports of entry for imported foods.

FMI believes this redeployment can be easily accomplished by the development of a cross-utilization program between USDA/FSIS and FDA that would allow for the sharing of resources for the inspection of imported produce and seafood.

Indeed, as part of his food safety initiative, the President has already announced creation of a Council on Food Safety to develop a comprehensive strategic plan for federal food safety activities and develop a coordinated budget for the agencies responsible for regulating food safety. The creation of this council, complemented by the work that this subcommittee and others in Congress have accomplished in recent years, sets the stage for just such a cross-utilization program.

However, should cross-utilization not prove feasible, the improved utilization of inspection personnel could still be accomplished by transferring statutory authority for

inspecting imported produce from FDA to USDA; or by transferring FSIS inspection personnel to FDA for reassignment to ports of entry.

Almost all of the other proposals for improving the safety of imported foods that we have seen require additional tax dollars. Fortunately, the resources and expertise necessary to put the plan we have proposed in place already exist within the federal government. It is simply a matter of coordinating resources among the affected agencies or redefining responsibilities as directed by Congress. **Consequently, all of the approaches I have outlined would be revenue-neutral.**

FMI understands that this proposal could meet resistance from both within the government as well as from industry. Debate, of course, is a necessary part of the democratic process. It enables us to forge better policies and ensure that legitimate views are represented. However, debate that does not reach a conclusion serves no one's interest. In today's media-oriented society, when issues play out in headlines and sound-bites, unending arguments over matters as important as food safety leave the public confused, frustrated and angry. Too often we do a masterful job of raising concerns — but a terrible job of resolving them.

This Subcommittee, under Sen. Collins' leadership, has raised awareness of the shortcomings of our imported food safety inspection system. It is now time to move on to the resolution of these problems.

Thank you Madam Chairwoman and members of the Subcommittee for the opportunity to speak with you today on behalf of the members of the Food Marketing Institute.

TESTIMONY OF STACEY ZAWEL, Ph.D.

DIRECTOR, SCIENTIFIC & REGULATORY AFFAIRS,

GROCERY MANUFACTURERS OF AMERICA

Good morning. My name is Stacey Zawel. I'm the Director of Scientific and Regulatory Affairs for the Grocery Manufacturers of America (GMA). GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $430 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues.

I'd like to talk today about the U.S. food supply, which remains the safest and most abundant in the world. Though we are very concerned about imperfections in the system, we should not lose sight of the fact that American consumers safely enjoy more than 750 million meals every day. GMA and the food industry have a great deal at stake in ensuring the safety of our products, and we take this responsibility very seriously.

While the primary responsibility of producing safe food lies with the food industry, FDA and USDA work in cooperation with us to help ensure the safety of our domestic food supply. These agencies must serve as guardians of the health and welfare of all Americans, especially with regard to the regulation of food imported into the United States.

However, to do this, FDA needs no further authority to enforce the law. Imported food is subject to requirements intended to ensure that food is safe whatever its origin. The U.S. Department of Agriculture has the explicit authority under statutes to regulate imported meat and poultry. The Food and Drug Administration has the authority to regulate imported seafood. The Federal Food, Drug, and Cosmetic Act grants the Department of Health and Human Services the authority to regulate all other food products. With very limited exceptions, the Food and Drug Administration has no explicit authority under the FFDCA to inspect foreign food establishments. However, the agency does inspect some foreign establishments on a voluntary basis.

Although the FFDCA provides FDA with no foreign inspection authority, it does authorize FDA to refuse admission to articles, including foods, that appear to be adulterated or misbranded, or that have been manufactured under unsanitary conditions. The Secretary of Health and Human Services also has the authority to refuse entry to foods that are illegal or subject to restrictions in the country in which they were produced or from which they were exported.

To streamline its import monitoring activities, FDA routinely issues import alerts to its district offices. These alerts identify products and importers that have repeatedly violated federal law. However, inspection at ports is only one part of a multi-faceted strategy to assure only safe foods are imported into the United States. To the extent port-of-entry operations can be improved through better management and resource allocation, we would support that effort. It is very important to recognize that inspection alone does not make food safe.

GMA believes that the system and scope of FDA authority, parts of which I've just described above are fundamentally sound. Rather than merely expanding inspection authority, GMA recommends three steps we believe will more effectively address those food safety concerns presenting the most significant risks to public health:

(1) -- conduct more research to identify foodborne hazards and habitats;
(2) -- allocate more resources to the appropriate prevention programs; and
(3) -- assert leadership in the international standard setting arena.

Now, I'd like to expand on each of these areas:

First, the agencies responsible for food regulation must be provided with the means necessary for essential scientific expertise and research. We have to identify and fight true causes of foodborne illness with the right scientific weapons, which can only be discovered through laboratory research and practical testing.

Without proper research supporting our food safety system, regulators won't be able to keep pace with today's manufacturing processes. An effective and credible science-based system complementing food manufacturers' own safety assessment programs provide consumers with the greatest assurance possible that their food is safe.

Second, the federal agencies overseeing the food supply need appropriate resources – that means money for scientists, investigators, state of the art scientific and technological tools, and modern, well-equipped physical facilities.

Consumers are best served by strong food safety agencies that develop policy based on the best science to build public confidence in the safety of the nations' food supply. With adequate resources, appropriately applied, they will be able to respond to the changing dynamics of food safety in a creative and effective manner.

Finally, we must assert strong government leadership in the global arena to stay on course and develop solutions to real food safety problems. Congress needs to provide funding and encouragement to FDA and USDA to play a more active and influential role at international meetings, such as in Codex Alimentarius. This means three things:

It means supporting workshops prior to Codex meetings to educate our trading partners, especially those in developing countries.

It means supporting the personnel needed to coordinate U.S. delegation activities.

And finally, it means building coalitions with other countries who participate in Codex to hasten the process of improving food safety systems worldwide.

The steps I've outlined may seem simple, but they're not simplistic. They require action based on science and common sense. GMA stands ready to assist Congress in any way we can to help further enhance the safety of the food supply -- in the United States and throughout the world.

Thank you for the opportunity to testify today. I welcome any questions you may have.

Testimony of Dane Bernard
Vice President of Food Safety
National Food Processors Association

Senate Permanent Subcommittee on Investigations
Committee on Governmental Affairs

Hearing on Federal Efforts to Ensure the Safety of Imported Foods

September 25, 1998

Madam Chairman, respected members of the subcommittee, ladies and gentlemen, I am Dane Bernard, Vice President for Food Safety at the National Food Processors Association. On behalf of our members with operations in all 50 states and points throughout the world, thank you for this opportunity to offer our comments on protecting, preserving and promoting the safety of America's enviable food supply. Coupled with the testimony we presented to the subcommittee on May 14th, we hope our views and observations will help with your thoughts on the subject.

Let me begin by noting that NFPA's testimony today reflects the expertise of our food scientists and those of our member companies, all of whom are dedicated to making the food we all eat affordable, abundant and as safe as possible, whether it's lobster from Maine, pineapple from the

Philippines, or vegetables from Mexico. To that end, NFPA frequently works with its members to develop, promote, and implement new and better ways to achieve these goals. In the process, NFPA has gained international respect as an authority on food science and food safety largely because of the skill, knowledge and dedication of NFPA's 60 plus scientists and regulatory experts.

Opening Observations

While I prefer not to begin with a digression, I think three quick points merit special attention to put our testimony in the proper context.

First, data on foodborne illnesses do not support claims that imports are inherently less safe than foods produced domestically. This doesn't mean the system can't be improved--some changes are warranted--and NFPA will work with authorities in this enterprise.

Second, those who believe our borders and ports stand agape waiting for cheap, contaminated food should understand that American processed food companies do not stand with arms spread wide ready to accept bad product.

American food companies have nothing to gain and everything to lose by bringing questionable food into our country and using it in processing

food. Losses in reputation, customers, sales, and so forth simply are not worth any illusionary savings that may arise from bad business practices or junk science. Then, too, beyond these cut-and-dried business calculations, reputable American food processors want to avoid health risks to every extent possible, not jeopardize their families and yours.

As such, U.S. food processors are aware of and have confidence in their international growers, producers and suppliers. It's a trust formed from a history of on-site inspections, of specifications for commodity production and food processing conditions, and of microbiological and chemical tests to verify high safety standards--all to ensure safe food.

In fact, the industry voluntarily conducts more tests and inspections than the federal government could run. The federal government does not stand alone to combat the importation of bad product--its agencies are a small part of a legion of food company scientists at work for America's consumers. Any suggestions we make to improve import control programs do not insinuate that the safety of imported food rests solely on what the FDA does or does not do.

Third, in order to improve FDA's methods and thus ensure its strength and durability as a link in the food safety chain, the food industry, associations, academia, and the general public must know what the FDA

proposes for the short and long terms. As part of this, the FDA must clearly identify what their regulatory plans are, explain how any changes would work, and how much they would improve the safety of imported (and domestic) food safety.

We recommend an annual publication of a regulatory agenda in the Federal Register which spells out the FDA's plans for implementing any new food safety programs. Finally, to help all of us help them, the agency must specifically cite what statutory authority it has or does not have to meet its agenda.

Overview

Working from this perspective, and focusing on imported food safety, NFPA supports policies that 1) concentrate on whether food is safe, not on its origins, 2) maintains that imported foods should be as safe as those produced domestically, and 3) affirms that foods must meet all relevant U.S. public health standards. To achieve these goals, we recommend that the United States reach accords with other nations that rely on determinations of equivalency based on sound science and risk assessment that are vigorously enforced in an appropriate manner.

Definitions

Madam Chairman, the outcome, effect and enforcement of laws and regulations often turn on the definitions of words. Three are essential to our take on imported food safety: "equivalent," "risk assessment," "science-based," and their derivatives.

By "equivalent" we mean "equal, as in value, force or meaning or having similar or identical effects," as defined in *The American Heritage Dictionary of the English Language.* This characterization is mirrored in *Black's Law Dictionary,* where "equivalent" means "just what the word 'equivalent' says--equal in value, force, measure, volume, power, and effect or having equal or corresponding import, meaning or significance . . . " "Equivalent" is not identical and it is not "the same as," except, as stated in both citations, in their results or effects.

(And let me quickly add that "equivalent" and "equivalency" are the same--the focus is the end results or effects.)

These concepts are important, if not essential, to a workable international food safety scheme. Just as several combinations of streets, roads, avenues and highways get you to the same place, several systems can produce safe food that meets our high expectations. Likewise, an automaker in the United States doesn't build automobiles using machines or procedures

identical to those operated and used by manufacturers in Europe or Asia, but safe, dependable cars come off both assembly lines nonetheless, and the desired result is realized.

In short, the food safety *systems*--the machinery of it all--may not be identical to what the U.S. prescribes for domestically produced food, but the results are "equal or identical in effect."

"Risk assessment" won't require any great linguistic review because the term means just what it says: An assessment of how great the chances of contamination are based on the intrinsic nature of a food product, the general level of sanitation in a country, or on a nation's commitment to export *safe* food.

"Science-based" shares the same straightforward quality--it means using "sound, proven, accepted, and objective scientific methods." The phrase does not include unfounded fears of aberrant occurrences of contamination, country of origin, subjective conclusions, or prejudices of any kind.

The GAO Report

Now that we have covered these important and necessary preliminaries, let me move through NFPA's thoughts and conclusions about the Government Accounting Office report.

Framework of Compliance: The GAO report recommends that the federal government discard end-product testing to verify food safety and, instead, promote systems that prevent contamination from occurring in the first place. We agree. Hacking away at the branches of a problem is far less effective than working on the roots.

We also agree that all imported foods should be produced under equivalent--not necessarily identical--food safety systems. NFPA cannot endorse legislation requiring other nations to adopt our exact procedures and certainly cannot in any way condone the mandatory imposition of methods that are "the same as" those in the United States unless no other method exists to ensure an equivalent level of protection.

To realize these ends, NFPA believes the superior route follows international accords like bilateral Equivalence Agreements, Memoranda of Understanding (MOU's), Mutual Recognition Agreements (MRA's), and similar avenues. Voluntary agreements promote cooperation and food safety; mandates only invite retaliation.

When following this road, the U.S. would emphasize the importance of another country's food safety plan as a whole and would assess the system using the best science available to determine if the food safety scheme was equivalent, or consistently capable of achieving the right results--adequate protection of the public's health.

Going back to our automobiles, the point is to concentrate on the *design* for each type of vehicle and if, when that design is properly implemented, safe cars would be produced, even if Ford's design differs from Audi's or that Audi buys steel from a different supplier than Ford. If indeed both vehicle designs can deliver the desired outcome, then both are acceptable, provided objective evaluations confirm the end result, like a series of test-drives in our car analogy.

Such verification would prove the dependability of the design, and, once proven, there would be practically no need to continue test driving each new vehicle, just as there would be a reduced need to test foods once the design and implementation of the production scheme have been validated.

Enforcement: While the entirety of the plan, the design of it, elicits general approval for importation based on sound science and risk assessment, producers must still complete the circle by following the

appropriate methods, and the country of origin must enforce the scheme. For our part, we must trust, but verify.

Within this construct, random, relatively frequent end product testing may come into play until a record of consistent compliance is established, at which time end product inspections would taper off to periodic unannounced examinations. The same would apply to in-plant, in-field inspections under an MOU or other voluntary accord: prove to be reliable in containing risk and your imports will meet with fewer obstacles.

If the evidence points to a pattern of negligence, however, the Food and Drug Administration would accelerate end product, in-plant and/or in-field inspections. FDA could establish a "three strikes you're out" regulatory threshold where importers with multiple safety-related violations would be targeted for very frequent and rigorous inspection if not out-and-out denial of entry.

For repeat offenders in this category, a permit system could be instituted which stipulates augmented checks on imported food products much like the FDA's domestic program for producers of canned goods. In other words, bad actors would have to obtain a "permit" from the appropriate agency before they could bring product into the U.S., and permits would be granted only after the safety of the goods is verified. A "need for a permit"

classification would terminate only after the importer re-establishes an appropriate level of trust.

Whether under the current scheme or some other arrangement, the FDA must seize greater control over our borders and ports, especially when repeat offenders are uncovered. Allowing rejected products to re-enter at another point cannot be tolerated. Noncomplying imports must be marked or otherwise identified so that end runs fail and those attempting such fraud are dealt with swiftly and effectively.

U.S. authorities must also prioritize infractions and responses according to the risks they pose. GAO's oft cited example of the FSIS ranking incorrect labeling that is not health related on the same par as true health-threatening infractions is ludicrous. At the very least, the example displays a disturbing disregard for employing food safety dollars to full effect.

Finally, the GAO hints at an accreditation system for laboratories to permit independent food testing by third parties. While the concept has merit, accreditation programs are expensive to establish and to maintain effective verification. Applying a "three strikes you're out" system based on random FDA sampling of laboratories' accuracy, compliance, and performance could achieve similar results. That is, rather than producing a

list of "accredited labs," FDA would identify those laboratories that do not produce adequate results.

Resources: Requiring food safety to have a sound science underpinning and placing the responsibility of ensuring the safety of food imports on the exporting countries allows the agency to target its resources and avoid health risks.

Still, some additional resources will further enhance the FDA's ability to combat contaminated imports. In the near future, resources will be needed to:

- establish MOU's with exporting countries in order to institute risk-based systems, to evaluate the effectiveness of current sanitary measures, and to enforce both;
- verify the accuracy of importer-provided shipping information; and
- to move repeat offenders from eligibility for electronic filing to only hard copy filing status when risky products are involved.

Also, the FSIS should modify its Automated Import Information System (AIIS) so that food safety infractions, high-risk products, and importers can be quickly and accurately identified.

Legislation

Allow me to very briefly comment on the need for legislation. NFPA respectfully submits that any legislative initiative, like the "Safety of Imported Food Act," should evolve deliberately. Frankly, we maintain that the FDA already has the statutory authority to make the changes, through regulation, that the GAO and others have suggested.

To confirm and clarify what legislation is and is not needed, and as a first step toward coordinating legislative and regulatory food safety initiatives, we recommend that the FDA outline for the Subcommittee the problems the agency has identified, their current authority to correct those situations and what regulations it foresees proposing to improve the safety of imported foods. If the agency thinks current authority is insufficient and new authority is needed to meet this challenge, it should identify those deficiencies and explain those shortcomings with specificity. The FDA should also present a detailed list of what changes in the law they deem necessary and why.

Congress, consumers, and the food industry would benefit from a thorough accounting of the FDA's intentions and the extent to which any new laws and regulations would reduce foodborne illnesses from imported foods. We encourage the Subcommittee to request this of the FDA.

After receiving FDA's analysis, if legislators, regulators, industry advocates and food scientists reach a consensus on food safety policy and the FDA demonstrates that legislation is needed to proceed, then Congress should do so. Our concern is that a "Fire, Ready, Aim" approach such as that embodied in current proposals would not produce the most desirable results.

Conclusion

Madam Chairman, I will now say two words that should please everyone here: "In conclusion." And I promise to be quick about it.

During the Great Depression, FDR enjoined his managers not to worry if this or that didn't work, just try something else, *but by golly try something!*

We most certainly are not in any Great Depression of food safety. We aren't even experiencing some very small, garden-variety recession of safety. We don't have to try something, by golly. In fact, the biggest danger facing us may be the damage caused by putting a sledgehammer to work when a little tack hammer would serve admirably, if not better.

Spending precious tax dollars to inspect everything from farm to table won't work. For example, the FSIS employs about 7,500 inspectors. If we

put 7,500 inspectors in every U.N. country (185), 1.4 million new examiners would be needed and the eradication of contamination could still not be guaranteed. More of the same rarely means better--just more.

If a desire to try something burns, then we need to act with common sense, and to our way of thinking, a risk-based, sound science approach would produce more bang for the buck and better food safety than any other method NFPA has encountered. That's a fairly good bargain in the change game.

Madam Chairman, thank you for inviting NFPA to testify. Of course, I would be pleased to answer any questions you or your colleagues may have.

Nancy Nagle, Ph.D.
Senior Adviser for Food Safety
United Fresh Fruit and Vegetable Association

Chairman Collins, thank you for this opportunity to testify before the Permanent Subcommittee on Investigations. I am here today on behalf of the United Fresh Fruit and Vegetable Association, as their Senior Adviser for Food Safety. I have extensive management and technical experience with both the production and handling of fresh fruits and vegetables, and processed foods.

The United Fresh Fruit and Vegetable Association (United) is keenly interested in the topic of food safety. Over 1,100 member companies and organizations make up United, an association that was founded in 1904. United is the national trade association that represents the interests of producers, wholesalers and distributors of commercial quantities of fresh fruits and vegetables. Our members take very seriously their responsibility to provide consumers with safe, high quality, nutritious produce.

I want to emphasize at the outset of my testimony that fresh fruits and vegetables are a remarkably safe product. Despite the recent attention that produce safety issues have received, United is convinced that alarming reports by the media and the fears of some public health officials far exceed the actual risks associated with the consumption of fresh fruits and vegetables. The evidence indicates that in the majority of cases, when the consumption of fresh fruits and vegetables has resulted in an outbreak of illness, the cause is often related to improper handling or cross-contamination with other potentially hazardous foods during food handling and meal preparation. Nonetheless, United is committed to enhancing the safety of produce and we welcome the publication of Food and Drug Administration (FDA) guidance.[1] We recognize that growers, packers, shippers and other handlers play an important role in assuring the safety of produce and we intend to use FDA's guidance to help prevent or minimize potential microbial hazards.

In the matter of produce safety, I want to make very clear that United knows of no information which indicates that the origin of produce is a significant factor in determining the safety of the produce consumed in the United States. We recognize that unique food safety risks and FDA enforcement challenges may be associated with imports of fresh fruits and vegetables, but the risk of consuming these products is at a comparably low level as domestically produced and handled products.

In the remainder of my testimony, I will turn to the questions specifically posed by the Subcommittee.

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[1] *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, this guidance document is expected to be published in the *Federal Register* during the first week of October, 1998.

What are the deficiencies in the current food import process and what can be done to address those problems?

United believes the Food, Drug, and Cosmetic Act (FFDCA) provides ample authority to FDA to assure the safety of fresh fruit and vegetables. Under the FFDCA, FDA is granted wide latitude to refuse the admission of imported food into interstate commerce. FDA may refuse the admission of such food if it appears from an examination, or otherwise, that a food --

- is adulterated,
- misbranded, or
- has been manufactured, processed or packed under insanitary conditions.

The terms "appear" and "otherwise" are key to the agency's statutory authority and allow FDA to take action against an article of food with much less evidence than would be required for a domestically produced food.

FDA has a clear understanding of its authority. In FDA's discussion of its automatic detention system, the agency writes in its *Regulatory Procedures Manual*, "Congress authorized FDA to refuse admission of regulated articles based on information, other than the results of examination of samples, that causes an article to appear to violate the [FFDCA]."[2] FDA also writes that the agency can consider an article's violative history, among other things, in determining whether or not future entries may appear violative. A more complete discussion of this authority is attached to my testimony in a memorandum, dated December 15, 1997, from United's legal counsel, Olsson, Frank and Weeda, P.C.

Some legal experts read the FFDCA as providing FDA the authority to inspect foreign food production and handling facilities. Section 704(a)(1) of the Act grants FDA clear authority to "enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce . . . ." The FFDCA defines "interstate commerce" to mean commerce between the United States and its territories and "any place outside thereof . . . ."

FDA's inability to provide more certainty as to the safety of imported fresh fruits and vegetables rests with a lack of resources. The General Accounting Office's April 1998 report on food safety clearly describes a situation where imported food entries are increasing at a substantial rate, while FDA's capacity to inspect is declining. The report notes that, ". . . FDA's inspection coverage of imported food entries has fallen from

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[2] *FDA Regulatory Procedures Manual (RPM)*, ch. 9 at 346 (Aug. 1995) (emphasis in original).

an estimated 8 percent of food entries in fiscal year 1992 to 1.7 percent in fiscal year 1997."[3] FDA must be given the necessary resources and personnel to provide better coverage over imported foods. Despite this unsatisfactory downward trend in FDA's inspection coverage, food safety does not correspondingly ebb and flow with the changing levels of FDA inspection. Fresh fruits and vegetables are consistently safe to consume because of strong and undeniable marketplace incentives to assure safety--not because of FDA inspections.

We also agree with GAO's determination that a reliance on port of entry inspections cannot provide complete assurance of the safety of imported foods. It is widely accepted among food safety professionals that prevention of microbial hazards is far more effective than trying to ascertain and verify the safety of food after its been produced and handled. United believes the approach taken by FDA and officials from the Centers for Disease Control and Prevention (CDC) to work with Guatemalan raspberry growers offers instruction on how to work cooperatively with foreign growers, packers and shippers of fresh fruits and vegetables.

As a result of efforts by FDA and CDC, growers who export from Guatemala have made tremendous strides in improving the general level of sanitation in the production and handling of raspberries. The impetus for these changes flows from a strong desire to produce a safe product, the threat of adverse publicity, and FDA's authority and stated intent to use its automatic detention authority to prevent the importation of Guatemalan raspberries. Where FDA believes a problem may exist with imported produce, the agency has established, through its experience in Guatemala, a clear road map on how to proceed.

More recently, an FDA official was in Sonora, Mexico meeting with state officials who are eager to implement the measures suggested in the agency's soon to be released guidance on preventing potential microbial hazards in produce. United sees few significant limits on FDA's ability to work with the producers and governments of foreign countries to enhance the safety of their food exports, except that the agency lacks needed personnel and resources.

Can the regulatory agencies better use their existing regulatory authority to improve the safety of imported food?

In addressing the first question, I have made clear United's view that FDA has ample authority to assure the safety of imported fresh fruits and vegetables. In fact,

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[3] *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, p. 25, General Accounting Office, April 1998.

given the perishable nature of produce, importers of produce view FDA's automatic detention authority as a very serious, if not impossible, hurdle to overcome. In the case of Guatemalan raspberries, the threat of automatic detention effectively foreclosed the possibility of successfully marketing that product in the United States because of its very short shelf life. Any delay in the marketing of such a perishable item by automatic detention, even if only by a few days, can terminate the commercial viability of that produce commodity.

Three important opportunities exist for FDA to move forward to create greater certainty that the foods we import are safe. Those opportunities are--

- the publication of FDA guidance to minimize and prevent microbial hazards in produce;
- the publication of guidance on the criteria FDA intends to use to evaluate whether or not a regulatory system used by a foreign country to ensure the safety of food is equivalent to that in the United States; and
- the pursuit of internationally recognized standards set by *Codex Alimentarius* for the hygienic production and handling of fresh fruits and vegetables.

As noted earlier in my testimony, FDA is expected to publish in the first week of October a guidance document intended to identify for growers and packers potentially significant microbial food safety risks and appropriate measures to prevent or minimize the occurrence of microbial hazards in produce. This document has captured the attention of governments worldwide, and of foreign grower and exporter organizations. There appears to be universal interest in understanding and using, where possible, the recommendations contained in the guidance. We believe that FDA working in concert with other U.S. government agencies, that have an international outreach mission, can have a very positive effect in elevating the awareness of produce food safety issues in countries that export to the United States.

FDA can take another important step, pursuant to the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures. According to the agreement, each member nation of the WTO is obligated to recognize another country's food regulatory system as equivalent, when it is determined that such a food regulatory system provides the same level of health protection as provided by the member country's own system. In June, 1997, FDA published for public comment a draft guidance on criteria that the agency intends to use in evaluating the equivalence of foreign food regulatory systems.

United believes FDA should finalize its draft equivalence criteria guidance document, move forward to ascertain the equivalence of foreign regulatory systems, and establish Mutual Recognition Agreements (MRAs), where possible. Such steps help provide FDA a rational means of allocating inspection resources, shifting resources away from countries with whom we have MRAs and focusing instead on those countries and products that may pose real food safety challenges. The only meaningful limitation to the agency in developing MRAs appears to be the lack of resources and personnel.

The *Codex Alimentarius* Committee on Food Hygiene will meet in October 1998 to review, among other things, a discussion paper, *Proposed Draft Code of Hygienic Practice for Primary Production, Harvesting and Packaging of Fresh Produce.*[4] We strongly encourage FDA to participate fully in this effort using its guidance document and to internationalize certain key concepts of preventing microbial hazards in produce. The Codex process represents an important opportunity to enhance food safety, assure a level playing field for U.S. and foreign growers, packers and shippers, and to minimize the possible disruptions in trade resulting from the development of differing standards.

United believes strongly that FDA has ample existing authority to assure the safety of imported foods. Also, FDA should dedicate a significant portion of its resources to work with foreign governments and international organizations in an effort to prevent imported food safety problems, rather than deal with them after the fact. In discussions among our membership, many of our members who grow, pack and ship from foreign locations have said they would welcome an FDA visit. These companies with foreign assets indicate that they exercise the same care and concern for food safety in their foreign activities as they do in their United States-based operations.

What other recommendations should be considered to improve the food import process?

In response to the Subcommittee's third question, I will take the opportunity to address imported food safety legislation which has the support of the Administration, S. 1707 and, its companion measure, H.R. 3052. United opposes S. 1707. We believe the legislation is unnecessary, would be disruptive to the international marketplace, and that U.S. growers, packers and shippers could not operate as viable exporters if foreign governments chose to exercise the same authority contained in S. 1707.

United has engaged in several discussions with FDA officials to ascertain how the agency would exercise the authority contained in S. 1707, if enacted. We still lack a

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[4] The Committee on Food Hygiene asked the Government of Canada to prepare this document, and they have taken the lead in this effort.

clear understanding of the agency's intention. Moreover, some of what the agency has indicated in private and public discussion regarding S. 1707 causes us concern.

Our chief concern is that S. 1707 would enable and embolden FDA to bar the importation of food from an entire country, or regions and localities within, based upon a general assessment of the adequacy of the system or conditions within that country. There is no mystery to the fact that some produce is grown, packed and shipped from some countries that have significant deficiencies in their public health infrastructure. This does not mean, however, that these fresh fruits and vegetables are not grown, packed and shipped in a manner that assures safety. The produce that you may buy from a street vendor in a Central American city is not the same produce that is exported to the United States. We cannot tolerate a policy that would allow FDA to indiscriminately deny the importation of safe food from countries that may otherwise have an inadequate system or infrastructure.

When one considers the decisive steps FDA has taken in the past to bar the importation of fresh fruits and vegetables, Chilean grapes and Guatemalan raspberries being the examples, we wonder how FDA intends to use the extraordinary power contained in S. 1707. Like many people throughout the world, many Americans have a latent bias against imported foods. In the event of a future controversy or public concern regarding imported food safety, S. 1707 could permit FDA to act in a broad and sweeping manner to prohibit the importation of foods from whole countries. We think such actions would be rash and highly damaging to the continued availability of a year-round supply of produce, and undermine our ability to export produce to other countries.

Conclusion

I hope the Subcommittee will realize that we cannot rely exclusively on FDA to assure the safety for fresh fruits and vegetables. In the end, those who actually grow, handle and market the produce that we consume are the same people on whom we must rely to assure the safety of these products. The produce marketplace is highly intolerant of unsafe food and will react swiftly and negatively to outbreaks of foodborne illness. Today, grocery retailers and restaurant operators routinely ask their produce suppliers what measures have been implemented to assure safety. Likewise, insurance carriers ask their grower, packer and shipper clients to take appropriate steps to minimize food safety related risks. The produce industry has made great strides here and abroad to identify potential sources of microbial hazards in fresh fruits and vegetables, and United's members are willing to implement prudent measures to prevent problems.

In the end, we need FDA to work cooperatively with the private sector to help give us the tools to prevent food safety problems, because FDA cannot possibly inspect all domestic and foreign produce production and handling operations, nor would that be a desirable use of resources.

In summary, United believes the following --

- FDA has substantial and sufficient authority under current law to deny the importation of unsafe foods;
- FDA already has the authority to inspect foreign food production and handling operations;
- FDA should work cooperatively with foreign governments and grower organizations to assure the adoption of appropriate food safety measures;
- FDA can take several important steps to help assure the safety of produce imports, including--(1) publication of good agricultural practices guidance, (2) finalization of criteria to ascertain equivalency of regulatory systems, and (3) work through Codex to internationalize hygienic produce production and handling practices; and
- Congress should allocate more resources to FDA to help the agency accomplish its mission.

Thank you for this opportunity to testify. I look forward to answering your questions.

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MEMORANDUM

December 15, 1997

BY TELECOPY

TO: Mr. John J. Aguirre
Vice President of Government Affairs
United Fresh Fruit and Vegetable Association

FROM: David L. Durkin
Christina M. Markus

RE: FDA Authority To Prevent Importation Of Raspberries From Guatemala

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This memorandum responds to your recent inquiry regarding the Food and Drug Administration's (FDA) legal authority to halt the importation of food products into the United States. In addition to United's interest in recent Congressional activity addressing FDA's authority over imported food in general, you specifically noted that, on November 20, 1997, FDA's Center for Food Safety and Applied Nutrition sent a letter to the Guatemalan Berry Commission, indicating that -- due to concerns about Cyclospora contamination -- the agency does not plan to allow entry, between March 15, 1998 and August 15, 1998, of fresh raspberries from Guatemala.

To implement such a decision, FDA presumably plans to issue an Import Alert, providing for automatic detention at the border of any covered product offered for entry into the U.S. As you are aware, FDA issues Import Alerts for products it considers likely to violate U.S. law. Once an Import Alert is in place, covered products are stopped at the border, and the burden is placed on importers to demonstrate that their specific products comply with the law. The detention of such a highly perishable commodity at the border will effectively halt shipments; importers will be unlikely to take the risk of shipping product in the hope that, upon arrival, the product could pass some yet-unspecified test for the pathogen.

FDA has developed its Import Alert system pursuant to section 801(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which grants the agency broad authority to control the entry of food into the United States. That section provides, in relevant part:

> The Secretary of the Treasury shall deliver to [FDA], upon [the agency's] request, samples of food . . . being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before [FDA] and have the right to introduce testimony. . . . If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions . . . , or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which is was exported, or (3) such article is adulterated [or] misbranded . . . then such article shall be refused admission . . . .

21 U.S.C. § 381(a). It is important to note that the statute grants FDA the authority to deny a food product entry into the U.S. if it merely "appears" to be in violation of the FFDCA -- the agency need not prove a violation in order to prevent entry. (By contrast, to remove a food product from the U.S. commercial stream, FDA must actually prove it is adulterated or misbranded in some manner, see generally 21 U.S.C. § 331.)

FDA interprets the statutory phrase "If it appears from the examination of such samples or otherwise . . . ." as authorizing its automatic detention system:

> Congress authorized FDA to refuse admission of regulated articles based on information, other than the results of examination of samples, that causes an article to appear to violate the [FFDCA]. Information such as an article's violative history, among other things, may cause an article to appear adulterated, misbranded, or otherwise in violation of the [FFDCA], as described in Section 801(a).
>
> ***Automatic detention, first used by FDA in 1974, is appropriate when there exists a history of the importation of violative products, or products that may appear violative, or when other information indicates that future

> entries may appear violative.[1] Automatic detention has the effect of reminding the importing community that FDA is a regulatory agency, not a quality control laboratory.

FDA Regulatory Procedures Manual (RPM), ch. 9 at 346 (Aug. 1995) (emphasis in original).

FDA has established general criteria for determining when automatic detention should be recommended. See RPM, ch. 9 at 347-349. With regard to country-wide Import Alerts, the agency has provided, for example:

> When there is evidence that a product from a specific geographical area or country could pose a health hazard, the appropriate Center or district should recommend automatic detention. In such cases, where there is also information that the product is likely to continue to be violative, it may not be necessary to collect and analyze a physical sample.
>
> Automatic detention may be recommended for products offered for import from a manufacturer, shipper, grower, geographical area, or country based on information showing a pattern of importation of articles that violate the [FFDCA]. The information in the recommendation establishing a pattern of continuous violations of the [FFDCA] should indicate that actions necessary to remove such violations have not been taken . . . .

RPM, ch. 9 at 348. Automatic detention also may be recommended for:

> Specific product(s) from a country or specific geographic area when:
>
> a. There are at least twelve (12) detentions in a recent six-month period or less; and

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[1] For example, FDA has suggested automatic detention may be recommended if information indicates a food was harvested from polluted waters, or that a product was manufactured/held under insanitary conditions or manufactured in non-compliance with good manufacturing practices. Indeed, the agency has noted that automatic detention may be recommended for an article with no prior history of detentions, if adequate information indicates future shipments may be violative. RPM, ch. 9 at 347.

b. These detentions represent at least 25% of the total shipments of that product examined in that time period as known to the recommending district or unit; and

c. These detentions represent a significant number of firms that manufacture, ship, or grow the product from the geographic area or country.

RPM, ch. 9 at 348 (emphasis in original).

Finally, FDA has provided general guidelines regarding removal from automatic detention. Very generally, removal may be based on evidence that the conditions that gave rise to the appearance of a violation have been resolved, and the agency has confidence that future product entries will be in compliance with the FFDCA. RPM, ch. 9 at 350.

* * *

We hope that this background information is useful to you. We would be pleased to discuss Import Alerts in greater detail, if you so desire. Please contact us if we can provide any further assistance.

OFW:cmm

Testimony of

Mohammad N. Akhter, MD, MPH
Executive Director
American Public Health Association

representing the

AMERICAN PUBLIC HEALTH ASSOCIATION

before the

Permanent Subcommittee on Investigations
of the
Committee on Governmental Affairs

United States Senate

at a hearing on

The United States Food Safety System for Imports

September 25, 1998

APHA Testimony, Permanent Subcommittee on Investigations, U.S. Senate
9/25/98
Page 1

Madam Chairman, members of the committee, I am grateful for the opportunity to speak with you today about how we can better ensure the safety of imported foods. I am Mohammad Akhter, MD, MPH, executive director of the American Public Health Association, representing over 50,000 public health professionals dedicated to advancing the nation's health, including many of the front-line workers whose everyday efforts are essential to ensuring food safety. I am pleased to testify on their behalf today.

You, Madam Chairman, have taken a leadership role on both the policy and funding fronts of food safety, and we commend and encourage your interest and dedication in this area. Thank you for holding this hearing, and for inviting us to testify.

The Safety of Imported Foods is an Important Public Health Problem

A recent report by the General Accounting Office commissioned by this committee found that U.S. Federal agencies cannot ensure that foods imported into this country are safe. Unfortunately, the experiences of our members and staff indicate that this is true. Our current system for inspecting imported foods is fraught with gaps and inconsistencies that hamper efforts to insure food safety.

According to the Centers for Disease Control and Prevention and (CDC) Council on Agricultural Science and Technology, 6 to 33 million cases of foodborne illness occur each year in the United Sates with as many as 9,100 deaths. Costs for those illnesses and deaths in medical treatment and lost productivity range from $6.6 to $37.1 billion each year. The uncertainty in those figures results from the fact that we as a nation do not know just how many cases of foodborne illness go unreported each year.

Furthermore, the percentage of imported foods in the U.S. diet is significant. USDA's Economic Research Service notes, for instance, that in 1995 55.3 % of fish and shellfish, 33.3 % of fresh fruits, and 11.7 % of fresh vegetables in the U.S. diet were imported. While there are year to year fluctuations, in general the proportion of imported foods in the U.S. diet continues to climb. Indeed without imported foods such as fruits and vegetables, U.S. consumers would not have the year-round selection for many items that they currently enjoy.

Imported food products have been associated with several recent foodborne disease outbreaks in the United States. In 1996 and 1997, CDC identified almost 2,500 people in 20 states, the District of Columbia, and Canada who became ill from *Cyclospora* associated with Guatemalan raspberries. In 1997, 270 people in five states were stricken with Hepatitis A most likely from frozen strawberries from Mexico. In 1995, 242 people in 17 states and Finland were infected with *Salmonella Stanley* from alfalfa sprouts originating in the Netherlands. The threat of illness resulting from imported foods is, unfortunately, well documented.

The great uncertainty in current estimates of foodborne illness in the United States are indicative of other problems our country faces in identifying, tracking, and responding to emerging infectious diseases. To date, we have not invested the resources necessary to develop surveillance networks that can efficiently and expeditiously identify and characterize emerging pathogens. In terms of combating foodborne illness and making sure resources are allocated where they are most needed, it is vital that Congress appropriate the necessary funds to build the Nation's emerging infectious disease surveillance and response networks such as FoodNet. We need to be thinking not just about the pathogens we know today to be a problem, we also need to be able to detect pathogens that may emerge or reemerge tomorrow.

With that introduction, I would like to now turn to the specific questions that have been posed by the committee.

1. **What are the deficiencies in the current food import process and what can be done to address them?**

The most obvious deficiency is the lack of consistency between the United States and foreign food safety standards. There are two steps to ensuring the safety of imported foods for consumption. First, since the standards we apply to foreign products derive almost totally from the standards we apply to domestic products, we must ensure that we have adequate safety standards and regulations for all food products that adequately address the risk of food borne illness associated with them. Second, we need to make sure that Federal agencies have the statutory tools and resources necessary to ensure that imported food products coming into the U.S. meet those standards.

A. The U.S. Needs To Continue To Strengthen Its Domestic Food Safety Standards

The 1990s have been a period of great change in our nation's food safety system. We have seen the introduction of more science and risk based systems of food safety regulation including hazard analysis and critical control point systems. Total quality management, good manufacturing practices, and good agricultural practices have also seen advances and increasing incorporation into national food safety regulations.

In APHA's view, there are additional areas where regulation can be strengthened. An example would be the production of fresh fruits and vegetables. While APHA recognizes that the Food and Drug Administration has taken an important step in developing draft guidance for producers of fresh fruits and vegetables detailing how to safeguard against contamination, we think it is likely that a voluntary program provides an insufficient level of safety. We think serious consideration needs to be given to making the guidance document or elements of it mandatory. Areas such as the microbiological quality of irrigation water, the use of untreated animal waste as fertilizer, and other likely avenues of contamination on the farm need to be addressed.

B. FDA Needs Equivalency Authority

Imported food products should be as safe as those produced domestically. The only effective way to ensure this is to require that foreign producers produce foods within a food safety system that provides equivalent protection to that for domestically produced food. It is virtually impossible to design an inspection system that could identify all dangerous microbial pathogens in products as they come across U.S. borders. The technology is usually unavailable, the cost would be prohibitive, and the testing would be incapable of assuring safety while still allowing the products entry into U.S. markets within a reasonable period of time.

Sampling regimens used currently in the U.S. food safety system are designed as indicators of process control rather than direct indicators of a product's safety. Since a testing regimen that would insure the safety of products entering the U.S. is not feasible, the best available option is to require exporting countries to ensure they have equivalent food safety systems.

Currently, the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) has the authority to require foreign countries to demonstrate "equivalence" before they are allowed to import meat and poultry products in to the United States. The Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS) lacks similar authority for the products over which it has jurisdiction. APHA believes that FDA should have the same authority to require foreign countries to demonstrate the equivalency of their food safety system for a product or class of products before they can import those products into the U.S. This puts the burden of ensuring safety on the parties who are in the best position to prevent and treat potential contamination, the foreign producers and their governments.

C. The Need for Better Knowledge about the Pesticides/Other Chemical Hazards In Foreign Foods

There is yet another class of foodborne agents about which we know little. These are the pesticides and other chemicals that may be present in both domestic and imported foods. The Food Quality Protection Act of 1997 made significant progress in reforming domestic regulation of pesticides in the human diet to recognize the importance of multiple exposures to particular chemicals, similar mechanisms of action for different chemicals, and the special vulnerabilities of infants and children to some chemical exposures. In thinking about improving the safety of imported foods, we cannot forget that pesticides and other chemicals can provide significant threats also that need to be accounted for. Any food safety system for imported foods needs to ensure adequate safeguards against the importation of foods with unsafe levels of pesticide or chemical residues or products which have been produced using banned products.

D. Inadequate Testing of Imported Foreign Products for Verification of Process Control

One of the most powerful tools that regulators have for insuring that domestic and foreign producers use their best efforts to ensure their products are produced safely is to require verification testing for microbial and chemical performance criteria. APHA believes that all high-risk products should have performance criteria that address the risk or risks of concern with that product. With meat and poultry products, for instance, FSIS does sampling for the presence of *Salmonella*. The testing functions, not to ensure food safety, but to establish a measure of process control. APHA encourages the use of performance criteria where appropriate for encouraging and monitoring process control. This is already done for meat and poultry products, and we think expansion to other products both domestic and imported needs further consideration.

2. Can the regulatory agencies better use their existing regulatory authority to improve the safety of imported food?

APHA believes that regulatory agencies can use their existing regulatory authority better to improve the safety of imported food, but that there are substantial roadblocks to achieving this. As noted previously in my remarks regarding the need for a unified food safety system, there are clearly a number of areas where FDA and FSIS could work together better. Similarly, as noted by GAO there seem to be areas where each agency could do a better job of targeting their resources and inspections. However, there also seem to be basic flaws in our current regulatory system that require fundamental reorganization and statutory changes to redress. APHA believes that while existing regulatory authority can be used to improve the safety of imported foods, it alone is insufficient to ensure the safety of imported foods at an adequate level. Continuing to rely on existing regulatory authority, we believe, will continue to put U.S. consumers at unnecessary risk.

The most fundamental change that needs to be made to improve the efficacy of our food safety system in general is the creation of an independent, single, federal food safety agency in which federal food safety activities could be centralized. Nothing else can fully address the fundamental inconsistencies, overlaps, competing priorities, and gaps that exist between the way different federal agencies regulate both imported and domestic food products. It is well known that FDA and USDA have significantly different approaches to regulating imported food products. Although such a move would clearly require statutory authorization, it would provide a much improved food safety oversight process by more efficiently using the regulatory authorities that already exist.

The President's commissioning of a food safety council is a step forward, but only a first step.

Such a council still does not solve issues such as having multiple oversight, authorizing, and appropriations committees in Congress. And it does not clearly vest any one authority with the power and authority to take the decisive action necessary to harmonize the disparate paths our agency choose for ensuring food safety. The problem is one that goes beyond efforts for better coordination. The problem is one of agencies performing similar functions that have different cultures, authorizing legislation, appropriations and oversight committees, and regulatory structures. There is a need for fundamental reorganization.

3. What other recommendations should be considered to improve the food import process?

A. The Need for Better Information

Targeting scarce resources to address the areas of greatest risk is axiomatic to good public health practice. Lacking the necessary information to make those determinations is often the essential factor that prohibits progress. We need to put far greater investment into developing the information systems that help officials make decisions. It is fine to talk about the need for more risk analysis and benefit-cost analysis, but if the information is not there to do them well what you will get is more uncertainty and the undermining of public confidence in the food supply. Congress needs to appropriate the necessary money to develop sound surveillance networks that can provide the necessary information to make sound risk management decisions.

To achieve the goal of targeting food safety activities to the hazards of greatest risk, significant investments need to be made in our nation's foodborne disease surveillance infrastructure. Current levels of research and surveillance funding are inadequate to establish the scientific information and technology bases that are necessary to achieve a food safety system where activities are targeted at the areas of greatest risk. With the improved information that would flow from enhanced research and funding, domestic agencies would be better able to ascertain critical points for observation and action in foreign food production systems.

The funding must be made available to allow the continuing development of FoodNet, PulseNet and chemical hazard databases. These systems need to be developed to the point where they can provide ongoing feedback regarding incidence and patterns of foodborne illness that help further target and refine food safety regulatory activities.

Funding also needs to be provided for better surveillance of the presence of pesticides and other chemicals in the human body. Currently there is only minimal funding for these activities in the National Health and Nutrition Examination Survey (NHANES). Providing adequate funding to develop NHANES as a tool would allow researchers to start generating national baselines for exposures to pesticides and other chemicals and the methodologies for better understanding the public health significance of current levels of pesticides and chemicals that we are commonly exposed to.

B. Keep Risk Assessment in Its Appropriate Context

APHA has noted an unfortunate tendency in risk policy debates to focus sole on risk assessment while largely ignoring areas such as risk management and risk communication that are just as important to ensuring the health of the public.

The Presidential/Congressional Commission on Risk Assessment and Risk Management in its Framework for Environmental Health Risk Management, Volume I addressed this issue extensively. The key point recognized in the report is that risk assessment is only one piece in the larger framework of managing risk generally:

> Risk management is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations. (Framework for Environmental Health Risk Management, pg. 1 (January 1997)).

At its basic level, risk assessment, in a food safety context, is intended to help risk managers and other stakeholders assess the potential harm posed by a pathogen, chemical, critical control point in a production process, temperature abuse in the home, etc. and how great the likelihood is that people will be harmed from it. However, it is already accepted that many foodborne pathogens represent unacceptable risks. The key question with these pathogens is what to do about them and what types of risk-based decisions are necessary to making wise use of scarce resources.

Risk assessment must be considered in the context of the risk-based decisions that have to be made. Along with developing better methodologies for microbial risk assessment, more resources need to be dedicated to issues such as:

- Helping officials decide how and when to issue advisories or recall products,
- How to involve necessary stakeholders,
- How to identify and incorporate community values into risk decisions,
- How to prioritize food safety issues,
- How to better target inspection efforts, and
- How to communicate with and protect at-risk populations.

C. Imposition of Adequate Civil Penalties

The majority of companies in the United States and many in importing countries also, do a solid job of ensuring food safety. It is clearly in the best interest of food producers to produce the safest product possible. The solid record of much of the industry lends support to the desirability of allowing flexible regulatory options for meeting food safety standards. Such an approach has largely been followed in both FSIS's and FDA's new HACCP regulations. However along with allowing flexibility comes an increased need to insure accountability and the current system of civil penalties appears inadequate to discourage violations of U.S. food import laws.

Just as there is a gradation of violations of food safety protocols, there needs to be a system of penalties tailored to fit the magnitude of the violation. Fines need to be tailored so that they are effective in discouraging actions that place the public's health at risk. Government agencies need authority to impose fines that are significant enough so responsible parties cannot treat them simply as a "cost of doing business".

Conclusion

Our food safety system for imported foods clearly needs to be strengthened. We have tried to identify some of these, based on the expertise and knowledge of our membership who are directly responsible in many instances for foodborne illness prevention and response. As a nation we must take action to ensure that our population is not put at unnecessary risk of preventable foodborne illness. The food import regulatory system is a key part of accomplishing that objective.

SAFE FOOD COALITION

888 Seventeenth Street, NW, Suite 800, Washington, DC 20006 (202) 822-8060

Statement of Carol Tucker Foreman,
Coordinator for the Safe Food Coalition and
Caroline Smith DeWaal, Director of Food Safety
for the Center for Science in the Public Interest
on behalf of
the Safe Food Coalition

before the United States Senate Committee on Governmental Affairs
Permanent Subcommittee on Investigations
Hearing on Federal Efforts to Ensure the Safety of Imported Foods

September 25, 1998
Washington, DC

Good morning. I am Carol Tucker Foreman. I am the Coordinator of the Safe Food Coalition, a group of consumer, public health, senior citizen and labor organizations that have worked together since 1986 to improve the nation's food safety system.[1] The Safe Food Coalition was instrumental in persuading the federal government to revise the hundred-year-old meat and poultry inspection system. I also served as assistant secretary of Agriculture for Food and Consumer Services from 1977-1981. This testimony I am giving on behalf of the Safe Food Coalition was prepared by Caroline Smith DeWaal, director of food safety for the Center for Science in the Public Interest. CSPI represents over one million consumers on issues related to food safety, nutrition and alcohol policy.

[1] Safe Food Coalition members endorsing this testimony are the Center for Science in the Public Interest, Consumer Federation of America, Food and Allied Service Trades Department of AFL-CIO, Government Accountability Project, National Consumers League, National Environmental Trust, Public Citizen, Public Voice for Food and Health Policy, Safe Tables Our Priority -- STOP, and United Food and Commercial Workers International Union.

I want to commend the Subcommittee for its excellent work on the topic of imported food safety, under the leadership of Senator Collins. The depth of research presented in the hearings has been noteworthy. The interest of the subcommittee members shows the importance of food safety to your constituents and the general public. And in fact, polling data shows that consumers are very concerned about food safety. A survey reported earlier this year in the *Morbidity and Mortality Weekly Report*, a publication of the Centers for Disease Control and Prevention (CDC), found that among public health priorities, 77% of California citizens surveyed said that "Ensuring that foods are free from contamination" was ranked as "top priority," second only to "Ensuring safe drinking water."[2] In a more recent survey released by the Grocery Manufacturers of America, nearly 80% of respondents had heard news about food safety in the last year, and nearly 50% of those surveyed said news about food safety has affected the way they handle and prepare food.[3] These data show that food safety is on the minds of many consumers, who are taking steps to minimize their risk of foodborne illness. But consumers can't protect themselves from all the hazards that are showing up in the food supply, especially those on fruits and vegetables.

On August 20, the National Academy of Sciences (NAS) released a report entitled *Ensuring Safe Food from Production to Consumption*. The NAS documented that, short of the President of the United States, no one person is really in charge of the safety of the nation's food

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[2] Centers for Disease Control and Prevention, "Public Opinion About Public Health - California and the United States," *Morbidity and Mortality Weekly Report*, Vol. 47, No. 4 (1998), pp. 69-73.

[3] Grocery Manufacturers of America Opinion Poll cited in "Labor Day Belongs in the Backyard, Not the E.R.: New Survey Shows 80% of Consumers Hear Food Safety Message - But is Everybody Listening?" *Grocery Manufacturers of America Press Release*, August 31, 1998.

supply. Today, food-safety responsibilities are spread between numerous federal agencies with conflicting missions and responsibilities, resulting in uneven coverage and enforcement, according to the Academy.

The National Academy of Sciences stressed the need for better science and clearer statutory mandates in conjunction with a more streamlined system to correct the current deficiencies. The NAS concluded that the current legal structure for food safety is based on laws that are "inconsistent, uneven, and at times archaic."[4] Further, the report says that these laws "often inhibit the use of science-based decision making."[5]

This Subcommittee has been examining one aspect of the problem documented by the National Academy of Sciences. On the issue of imported foods, the NAS report says that the different systems utilized by the HHS's Food and Drug Administration (FDA) and the USDA's Food Safety and Inspection Service (FSIS) "largely mirror their different approaches to domestically produced food as is required since they must document domestic equivalence. History and statutory mandate, rather than scientific rationale, lead USDA to demand carcass-by-carcass inspection domestically. FDA, with its smaller budget, aspires to examine imports thoroughly but cannot do so. Neither approach is based on a rigorous assessment of risk."[6]

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[4] Institute of Medicine, National Research Council, *Ensuring Safe Food From Production to Consumption*, (Washington, D.C.: National Academy Press, 1998), p. 9 [hereafter cited as *NAS Report*].

[5] *NAS Report*, p. 8.

[6] *NAS Report*, pp. 48-49. Members of the Safe Food Coalition do not endorse the NAS view of carcass-by-carcass inspection. This quote is used simply to illustrate how the inconsistencies in domestic inspection can impact how the U.S. conducts inspections of imported food. Member organizations believe that well-designed studies are needed before any changes are made to the slaughter inspection system. These studies should determine the extent to which carcass-by-carcass inspection is needed to assure the safety of meat and poultry products.

Therefore, as you consider how to amend the current systems of assuring the safety of imported foods, it is important to remember that you are just seeing one corner of a much more complicated food safety puzzle that impacts both the safety of the food supply and the effective use of government resources.

OUTBREAKS AND RECALLS LINKED TO IMPORTED FOODS

In the past few years, there has been a dramatic increase in food imports. We have also seen a rise in the reporting of food-poisoning outbreaks linked to imported food, although no one is certain whether that association reflects a real increase in outbreaks. We do know, however, that the bacteria, viruses and parasites that contaminate imported foods can be different from our home-grown varieties.[7] That can prolong the time it takes to treat illnesses and identify the tainted food source.[8]

CSPI compiles a list of outbreaks that are reported either through CDC and state health department reports, scientific journal articles or well-documented press reports. CSPI has become aware of 14 outbreaks since 1990 linked to imported foods, not including meat and poultry products. The implicated foods include cantaloupe, crab meat, coconut milk, tuna, scallions, savory snacks, alfalfa sprouts, raspberries, cheese, strawberries, blue marlin, and a seafood product called limpets. The countries-of-origin include Ecuador, Mexico, Thailand,

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[7] E.C. Todd, "Epidemiology of Foodborne Diseases: A Worldwide Review," *World Health Statistical Quarterly*, Vol. 50, No. 1-2 (1997), pp. 30-50.

[8] Ynes R. Ortega, et al., "Isolation of *Cryptosporidium Parvum* and *Cyclospora Cayetanensis* from Vegetables Collected in Markets of an Endemic Region in Peru," *American Journal of Tropical Medicine and Hygiene*, Vol. 57, No. 6 (1997), pp. 683-686. It is difficult to identify *Cyclospora*, and the exact mechanisms of transmission are still unknown.

Portugal, Israel, Netherlands and Guatemala. It is important to note that while these data clearly demonstrate that there is a problem with imported foods, we also know that there are major problems with domestic foods.[9] See Attachment I.

In addition, using USDA data, CSPI has identified nearly 20 recalls linked to imported meat and poultry products for reasons ranging from microbial contamination to illegal drug residues to contamination with flies. These products came from Spain, Canada, Mexico, Dominican Republic, Netherlands, Israel, Brazil and Denmark. See Attachment II.

These outbreaks and recalls further document that contaminated foods are not being caught at the border. Frequently, problems are not discovered until after the foods have been distributed in the United States.

IMPROVING THE SAFETY OF IMPORTED FOODS

The Subcommittee has done an excellent job in highlighting the inadequacies in the existing programs. The Subcommittee should consider a two-step approach in addressing these problems. In the short run, it is critically important to recognize the gaps that Congress could fix this year by giving the FDA more resources and authority to improve its oversight of imports. In the long run, the existing food safety programs should be unified under a single agency with new statutory authority to ensure that the federal food safety program can make the best use of existing resources.

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[9] "Partial Listing of Outbreaks Traced to Meat and Poultry, 1990-1998", Compiled by Center for Science in the Public Interest, August 27, 1998, "Partial Listing of Outbreaks Traced to FDA-Regulated Foods, 1990-1998," Compiled by Center for Science in the Public Interest, September 11, 1998.

1. FIXING FDA'S IMPORT OVERSIGHT PROGRAM

To address the acute inadequacies in the FDA's oversight of imports, there are several steps that this Congress could take. The first and most important is to fund the President's Food Safety Initiative, especially the portion that is pledged to improve the inspection of imports. Under the Harkin amendment to the Agriculture Appropriations Bill, which was overwhelmingly passed by a bipartisan majority on the floor of the Senate, FDA would be entitled to over $27.6 million in new money for import inspections. This money is critically needed, and Congress should act quickly to assure that the agency receives the money.

Second, this Congress has before it a number of bills that would enhance the FDA's oversight of imported foods. The Safety of Imported Foods Act, S. 1707 and HR 3052, would give FDA specific authority to reject food from foreign countries that have denied FDA inspectors access to review growing and processing conditions. The Imported Food Safety Act, HR 4080, would charge a modest fee to importers to improve both border inspections and to conduct more research on real-time tests to improve FDA's import surveillance capabilities. Finally, the Consumer Food Safety Act, HR 3676, would require both domestic processors and importers to register with FDA and would require routine inspections of all high-risk processors, both domestically and in exporting nations.

These bills are all supported by the Recipe for Safe Food Campaign, a legislative and grassroots campaign to give the government better tools to clean up America's food supply. This campaign is a joint project of the Safe Food Coalition and the Center for Science in the Public Interest. Passage of any of these bills would be an improvement on the existing food safety system.

If members of this Subcommittee want to file separate legislation to improve the safety of imported foods regulated by FDA, it should include the following elements:

- New funding for food safety inspectors, both for border inspections and for on-site inspections in foreign countries.
- A certification program for exporting countries that can demonstrate that importers meet the same level of protection, with respect to food products, as required of U.S. growers and processors to assure safety. This evaluation should include a consideration of the health, sanitary, environmental, or other conditions within the foreign country that might adversely affect the safety of the food.
- Registration of importers, perhaps with a small fee, to ensure that facilities are sanitary and are approved to export from certified countries, with ongoing government oversight. Withdrawal of registration could occur if conditions change in the country or if the importer fails to comply with a voluntary or a mandatory recall.
- A specific mandate that FDA have the ability to visit any of our trading partners at any time to inspect any processors or growing and packing establishments that export products or intend to export products to the U.S. If U.S. inspectors are denied access, then FDA should have the discretionary authority to exclude food from that country.
- A specific mandate for border inspections that ensures that more shipments are inspected and tested at the border.

- Mandatory detention and recall, together with criminal and civil penalty authority, to ensure that contaminated food can be pulled from the market and that importers can be appropriately penalized for non-compliance.[10]
- Farm-of-origin labeling for both domestic and imported products. Farm-of-origin labeling would facilitate traceback and recall efforts, which would create greater accountability for food safety problems.
- Whistleblower protection for the personnel in foreign countries that have responsibility for enforcing the food safety laws.

2. DRIVING TOWARD A UNIFIED FOOD SAFETY SYSTEM

The Subcommittee cannot look at imported foods in a vacuum. As the National Academy of Science has documented, the differences in treatment of imported food at FDA and at USDA are simply an outgrowth of domestic differences between the programs. Current trading agreements require that we cannot have more stringent standards for imported food then we have for domestic food, so any improvement in the oversight of imports necessitates improvements on the domestic side as well. Otherwise, the U.S. may be found to be in violation of our trading agreements.

In the short term, improving FDA's food safety program is important to reverse the continuing decline of the program. However, it would take hundreds of millions of dollars to make FDA's food safety program fully equivalent to the USDA program on food safety in every

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[10] A 1987 case documents the problem of food firms refusing to comply with an FDA voluntary recalls. FDA initiated a recall of Royal Line brand smoked salmon imported from Denmark due to contamination with *Listeria monocytogenes*, but the distributor, Marcos Marketing of Marietta, Georgia, refused to cooperate. John Briley, "FDA Options Limited in Dealing with Uncooperative Firms in Recalls, Salmon Case Shows," *Food Chemical News*, August 18, 1997, p. 14.

respect. USDA's food safety system is also antiquated and subject to conflicting missions, so using that system as a model would not be in the best interests of consumers. In the long run, the only way to build a science-based and hazard-based food safety system that makes better use of government resources is to combine food safety functions into a single independent food safety agency. That is the approach proposed in the Safe Food Act, S. 1465, sponsored by two members of this Committee, Senators Richard Durbin and Robert Torricelli, and strongly endorsed by the Recipe for Safe Food Campaign.

The National Academy of Sciences has recommended in its recent report that a single federal official be given both statutory and budget responsibility for food safety. The NAS recommendation should provide the groundwork for the Subcommittee's future action in improving the food safety program. I hope that we can work closely with the Subcommittee on its future proposals.

A NOTE ON EQUIVALENCE

Finally, I would like to leave you with some thoughts on the concept of equivalence, which has been a major focus of the investigation of this Subcommittee. Equivalence is the process of evaluating other countries' food safety programs to determine that they meet the same food safety outcomes as the U.S. programs. It is critically important that public health, and not trade considerations, provide the underpinning for equivalence negotiations. American consumers are not willing to lower our food safety standards to improve our nation's trading status. In addition, differences between countries cannot be fairly evaluated simply by looking at rules and regulations. Regulators must be free to consider differences in worker sanitation, public health conditions, water, weather, the environment, and even the transportation infrastructure in making equivalence determinations.

Therefore, if the Subcommittee sets standards for equivalence in legislation or elsewhere, it is crucial that the Subcommittee make clear that protecting the public health is the paramount objective of the provision and require that government agencies consider all factors that may have an impact on food safety.

Attachment I
Partial Listing of Outbreaks Linked to Imported Foods,
FDA-Regulated Foods, 1990-1998

	Date	Vehicle	Country of Origin	Etiology	Reported Cases	States/ Provinces
1	1990	Raw scallops	South America	*E. coli* O153:H45	1,400	2 U.S. Cruise Ships
2	April 1991	Crab meat	Ecuador	*Vibrio cholerae*	12	2: NY, NJ
3	June-July 1991	Cantaloupe	Mexico	*Salmonella poona*	400	23/Canada
4	Aug. 1991	Coconut milk	Thailand	*Vibrio cholerae*	4	1: MD
5	April-May 1992	Tuna	Ecuador	Scrombold-fish poisoning	74	Eastern seaboard
6	February 1994	Limpets	Portugal	Norwalk-like virus	12	2: MA, RI
7	June- Aug. 1994	Scallions	IL, Mexico	*Shigella flexneri*	171	2: IL, MN
8	Oct 1994- Jan. 1995	Peanut flavored savory snack	Israel	*Salmonella agona*	10/27/2,200	US/UK/Israel
9	March- July 1995	Alfalfa sprouts	Netherlands	*Salmonella stanley*	242	17/ Finland
10	May- June 1996	Raspberries	Guatemala	*Cyclospora cayetanensis*	1,465	21/2: ONT, QUE
11	Nov. 1996- Jan. 1997	Cheese (homemade, unpasteurized)	Mexico	*Salmonella typhi*/ Hepatitis A	9/14	1: FL
12	1997	Raspberries	Guatemala	*Cyclospora cayetanensis*	1,012	18/Canada
13	Mar. 1997	Strawberries (frozen)	Mexico (implicated)	Hepatitis A	270	1: MI
14	May 1997	Blue marlin fish	Ecuador	Scromboid-fish poisoning	28	1: DC

Compiled by CSPI
Updated September 22, 1998

Attachment II
Partial Listing of Recalls Linked to Imported Foods
USDA-Regulated Foods, 1994-1998

	Date Case Opened	Date Case Closed	Country of Origin	Vehicle	Contaminant	Pounds Recalled	Pounds Recovered
1	Mar. 1994	Aug. 1994	Brazil/USA	Mexican Style Foods	Flies	159,292	131,631
2	May 1994	July 1994	Denmark/ USA	Cooked Ham	*Listeria*	844	806
3	June 1994	Sept. 1994	Brazil/USA	Beef Taquitos	Spoilage Bacteria	150,000	143,000
4	July 1994	Sept. 1994	Israel	Cooked Chicken Breast	Sulfadimetho-xine	8260	0
5	Feb. 1995	April 1995	Netherlands	Canned Luncheon Meat	Drug	0	0
6	Mar. 1995	Aug. 1995	Canada	Pork Shoulder Butts	Sulfamethazine	6,800	5,330
7	July 1995	July 1995	Canada	Hot Dogs	*Listeria*	11,420	0
8	Sept. 1995	Jan. 1997	Netherlands	Canned Luncheon Meat	Sulfamethazine	31,198	5,058
9	Oct. 1995	April 1996	Canada	Hot Dogs (Beef)	*Listeria*	3,510	3,010
10	Nov. 1995	April 1996	Canada	Hot Dogs (Pork)	*Listeria*	4,320	1,691
11	Dec. 1995	Feb. 1996	Netherlands	Canned Luncheon Meat	Sulfamethazine	1,476	1,314
12	Mar. 1996	June 1996	Dominican Republic	Cooked Salami	Sulfamethazine	1,725	330

Attachment II
Page 2

	Date Case Opened	Date Case Closed	Country of Origin	Vehicle	Contaminant	Pounds Recalled	Pounds Recovered
13	June 1996	Jan. 1997	Mexico	Ground Beef Patties	Penicillin	38,400	38,400
14	June 1996	Oct. 1996	Canada	Beef Jerky	*Listeria*	360	345
15	May 1997	N/A	Canada	Cured Pork Feet	Excess Sodium Nitrite	39,250	4,975
16	Aug. 1997	Jan. 1998	Croatia	Roast Beef w/ Gravy	Sulfamethazine	6,908	6,498
17	June 1998	N/A	Canada	Dry Sausage	*E. coli* O157:H7	15,000	8,578
18	July 1998	N/A	Spain	Serrano Ham	Sulfamethazine	3604	N/A

Compiled by CSPI from USDA data
Updated September 22, 1998

TESTIMONY OF
DR. RUTH KAVA, Ph.D., R.D.
THE AMERICAN COUNCIL ON SCIENCE AND HEALTH
BEFORE THE
SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
SEPTEMBER 25, 1998

Background

While food safety in the United States has been and continues to be very good, outbreaks of foodborne illness and deaths attributable to such illnesses have caught the attention of the public, the media[1] [2], and governmental agencies. The perception that such outbreaks are increasingly frequent and serious are prompting queries into the best means of reducing their frequency and extent.

The Centers for Disease Control and Prevention[3] estimated the direct and indirect costs of foodborne illness due to six bacterial pathogens as between $2.9 and $6.7 billion during the period 1991-1993. This estimate does not include illnesses due to other food- and water-borne pathogens such as protozoan parasites (e.g., *Giardia, Cyclospora, Cryptosporidia*) or viruses (e.g., hepatitis A, rotavirus). The total economic burden of foodborne illness is thus substantial, and, because foodborne illnesses are usually seen as underreported, likely to be greater than the estimate above would suggest.

Besides these large current economic costs , there are reasons to believe that the burden of foodborne illness will increase in the United States in the future. Even if the level of food safety were not to change appreciably, anticipated demographic changes suggest that there will be an increased proportion of the population that is more vulnerable to foodborne illness. Such changes include an increased proportion of elderly people, and more individuals with compromised immune systems due to disease and/or treatment.

The true extent of morbidity and mortality due to foodborne illness is not known with precision. It is generally recognized that foodborne illness is an underreported category of illness. Although statistical estimates of these parameters which try to account for underreporting have been published recently[4], their accuracy is unknown.

Imported Food Safety

Between 1983 and 1997 there were at least 17 outbreaks of foodborne illness in which imported foods were suspected if not proven sources[5] of pathogens.

One question that arises is the comparative safety of domestic and imported foods: do imported foods and food products represent more of a risk of foodborne illness than do their domestic counterparts – do we need special measures to deal with imported foods? The information

from the CDC cited above does not distinguish between outbreaks of foodborne illness due to domestic versus imported food and food products.

Foodborne illness outbreaks traceable to imported foods have received widespread media coverage,[1] and have left the impression with some consumers that imported foods are less safe than those produced domestically. A recent report by the USDA, however, indicates that there are not sufficient data to determine if this is really true.[6] Indeed, of thirteen outbreaks traced to fresh produce between 1990-96, only four (31%) were thought attributable to imported foods.[6]

The importation of foods and food products has increased substantially (in 1996 imported foods accounted for approximately 21 percent of domestic fresh fruit and vegetable consumption)[6]; since 31% of traceable outbreaks from such foods were due to imports, it might appear that they account for a slightly greater proportion of illness. Because the number of traceable outbreaks was small, it is difficult to judge whether this is really the case. However, since the volume of imports is likely to increase, it is important to examine the procedures upon which we rely to maintain imported food safety.

ACSH Position

- Data on the true extent of foodborne illness traceable to imported foods seems fragmentary. We recommend that estimates of such occurrences be improved – via increased surveillance, improved technical monitoring and testing.

- The GAO report indicates that there are major discrepancies between the responsibilities of the FDA with respect to maintaining imported food safety, and the resources which that agency is given in order to perform that function. FDA faces an increasing volume of imports but has a static number of inspectors, insufficient financial resources, and a lack of legal authority compared with that granted to the USDA. We therefore recommend that these discrepancies be eliminated, and that Congress take steps to enable FDA to perform its regulatory functions efficiently.

For example, it seems reasonable to shift some of the burden of ensuring the safety of food imports to countries wishing to export food to the U.S. by establishing mandatory equivalence requirements for imported foods (like those of USDA). FDA responses to the GAO report reflect some agency concern that such requirements will impair relationships with trading partners. It would seem reasonable to provide a sufficient period of time before requirements are made mandatory so that other countries can comply without undue hardship. Further, in designing an equivalence program, attention should be given to the possibility that FDA, other agencies alone or in combination with the private sector, could provide training and support for those partners who request it.

- Some groups have recommended that all federal food safety functions be combined under the control of a single, new agency, perhaps to be called the Food Safety Administration. It is not clear how such a reshuffling of responsibilities and agencies will quickly improve the safety of

imported foods. Indeed, since such a reorganization could take a substantial amount of time to initiate and organize, it might well be the case that food safety oversight would be impaired.

It would thus be more efficient to improve the resources of current agencies and eliminate any intra- or inter-agency redundancies or other factors that detract from the appropriate oversight of food safety functions.

- Efforts to improve the safety of imported foods should focus on proven health risks – the microbiological pathogens in particular, and also naturally occurring toxins. There is concern in the public sector about the safety of various pesticide residues, but there is no credible scientific evidence that such substances, when used in legal amounts, have caused any illness in the U.S. population. Indeed, some scientists note that when compared to the background of naturally-occurring chemicals that can cause cancer in lab animals, residues of synthetic pesticides do not rank high in possible carcinogenic hazard.[7]

- Allocation of resources should be based on up-to-date scientific information. Development of state of the art detection and testing procedures are therefore of primary importance.

- Under-utilized but proven methods for improving food safety, especially food irradiation, should be vigorously promoted. Their approval and official guidelines for their uses should be expedited.

- Some significant educational initiative must be a part of any efforts to improve the safety of foods – imported or otherwise. New campaigns to educate consumers about the proper handling of foods have been started (e.g., the "Fight Bac" program), but additional programs should also target other aspects of the food safety issue – for example, the fact that it is impossible to ensure zero risk with respect to food safety. Better understanding of risk assessment would help the public discern the difference between real and hypothetical food safety issues.

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2. Tainted Food Still Manages to be Imported into the U.S. *The Providence Journal*. September 11, 1998. p.A8.

3. Centers for Disease Control and Prevention. Preventing Emerging Infectious Diseases: A Strategy for the 21st Century. MMWR 1998; 47 (RR-15):2.

4. Council for Agricultural Science and Technology. Foodborne Pathogens: Risks and Consequences. 1994.

5. FOOD SAFETY: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable. GAO/RCED-98-103.

6. Zeep, G, Kuchler F, and Lucier G. Food Safety and Fresh Fruits and Vegetables: Is There a Difference Between Imported and Domestically Produced Products? Vegetables and Specialties/VGS-274; April, 1998; 23-28.

7. Gold, LG, Slone, TH, Stern, BR, Manley, NB and Ames, BN. Possible carcinogenic hazards from natural and synthetic chemicals: setting priorities. IN: CR Cothern (ed) *Comparative Environmental Risk Assessment*. Lewis Publishers, London. 1993. pp 209-235.

STATEMENT OF ROBERT HAHN
DIRECTOR OF LEGAL AFFAIRS AND RESEARCH

Madam Chairman and Members of the Subcommittee:

Good morning, My name is Robert Hahn, Director of Legal Affairs and Research at Public Voice for Food and Health Policy, a non-profit consumer research and advocacy organization that seeks to ensure a safe, nutritious and affordable food supply. Public Voice has paid particular attention to food safety since its founding in 1982.

We want to thank you, Senator Collins, and this Subcommittee for bringing to light serious problems with our system for ensuring the safety of imported foods. Although I'm not aware of any polling data, it is clear that this is an issue on the minds of many consumers.

The General Accounting Office report[1] and the previous four hearings of this Subcommittee present *a tale of two systems*: one run by the Department of Agriculture for meat and poultry imports and the other by the Food and Drug Administration for all other foods.

The USDA system involves a determination that each exporting country's inspection system is "equivalent" to ours, periodic on-site inspections by USDA personnel of meat and poultry plants in the exporting country, and re-inspection at the border of shipments of meat and poultry entering the United States.

The FDA system for all other foods relies almost exclusively on border inspections of imported foods. Yet, only a small percentage of imports are actually inspected. In recent years, the volume of FDA-regulated imports has skyrocketed while the number of FDA inspectors checking them has plummeted. The result is that last year less than two percent of imports were either visually inspected or lab tested. We have been told that it is easy for unscrupulous importers to circumvent the system in any number of ways, including "port shopping," misrepresenting the contents of shipments, substituting samples for lab testing, and substituting foods to be destroyed or re-exported, to name a few. Even when the system works perfectly, it cannot catch certain pathogens, like *cyclospora*, which cannot be detected even with lab tests. Not surprisingly, most of the recent outbreaks of foodborne illness associated with imported foods have been caused by FDA-regulated products. Clearly, the FDA system is inadequate and needs to be updated.

Naturally, the first order of business should be for FDA and its partner, the Customs Service, to do what they can to improve border inspection. Many of these improvements can be accomplished without Congressional action. However, we agree with the GAO that, given the increasing volume of imports and resource constraints on the FDA, border inspection will probably never offer American consumers a sufficient

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[1] Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable (GAO/RCED-98-103, April 30, 1998).

level of protection. That is why Congress should give FDA equivalency authority, the authority to bar imports from countries with food safety systems not equivalent to our own. Equivalency authority is crucial, because it shifts the burden of proof from an overworked, understaffed FDA trying to catch microbes at the border to the exporting country.

FDA AND CUSTOMS CAN MAKE BETTER USE OF EXISTING STATUTORY AUTHORITY

First, there are ways in which FDA and the Customs Service could use their existing statutory authority more effectively. Most of these measures have been mentioned by GAO officials or other witnesses, and we understand that FDA and Customs have begun to make some of these changes.

1. FDA should give its inspectors more information concerning the health risks associated with particular foods.

2. FDA should attempt to standardize procedures among the various ports of entry in order to discourage "port shopping."

3. FDA should devise a way of identifying and maintaining a list of importers with a history of food safety-related violations. According to GAO's testimony on September 10, FDA is in the process of developing such a system.

4. Customs should order importers with a history of violations to use independent bonded truckers and independent bonded warehouses to transport and store shipments pending inspection, all at the expense of the importer.

5. Samples of shipments for lab testing should always be collected by FDA inspectors, and all testing should be done by either an FDA lab or an accredited private lab. Currently, when a shipment is placed under "automatic detention," lab testing is required, but the importer is allowed to select the lab and may often also choose the sample. This creates an enormous opportunity for unethical importers to commit fraud and should not be allowed.[2]

6. FDA and Customs should devise a system to ensure that Customs is always

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[2]A procedure and criteria for lab accreditation are being finalized by a working group comprised of government agencies, professional organizations and private labs. The American Association for Laboratory Accreditation will likely be the accrediting body. Once this accreditation process is up and running, which should occur within a year, there will be no reason for FDA to allow an importer to use an unaccredited lab.

notified when a shipment is refused entry so that Customs can send the importer a notice to redeliver the shipment for proper disposal.

7. Customs should increase the penalties for food safety-related violations. In addition, Customs should be more relectant to mitigate fines and less reluctant to impose criminal penalties, especially where a violation puts the public at risk of serious foodborne illness.

CONGRESS SHOULD GIVE FDA ADDITIONAL AUTHORITY TO IMPROVE BORDER INSPECTION

In addition, there are measures to improve border inspection that FDA and Customs cannot take unless Congress grants these agencies additional statutory authority:

1. Congress should authorize FDA to require the registration of all food processors and importers and to charge them a nominal registration fee. Registration should include the owner's Social Security Number, so that an importer with a history of violations cannot simply change its corporate name to hide its record of violations.

2. FDA should have the authority to stamp refused shipments with the words "refused entry" to make it more difficult for rejected shipments to be distributed in U.S. commerce.

3. FDA should have the authority to levy civil fines against importers that violate the law. The amount of such fines should be sufficient to deter illegal conduct.

4. If a shipment is found to be adulterated after it has already been released into commerce, FDA should have the authority to order a mandatory recall of that shipment.

5. FDA should have the authority to require that importers use only accredited labs for testing.

6. Congress should reduce the 90-day time period that an importer now has to redeliver a refused shipment of FDA-regulated foods, in order to lessen opportunities for substitution.

While it does not relate to border inspection, Congress, FDA and USDA should also consider requiring labeling on all foods, domestic and imported, that would permit traceback to the processor or farm of origin in case such food is implicated in an outbreak of foodborne illness.

CONGRESS SHOULD GIVE FDA EQUIVALENCY AUTHORITY

While improving border inspection is important, giving FDA equivalency authority is the long-term solution to the problem of unsafe imports. Equivalency authority is the authority to require that an exporting country has food safety systems equivalent to our own before it can export to the United States. If an exporting country cannot demonstrate equivalency or if it denies FDA access to its facilities, then FDA could ban imports from that country.

Perhaps I can explain the need for equivalency with a personal observation. I traveled in China this summer. I had a great time, but by the time I reached Hong Kong I was dying for a salad. The fact is that in China and probably in many other developing countries, people do not eat uncooked vegetables the way we do in this country. And one of the reasons they don't eat uncooked vegetables is that they know that they're grown and transported under conditions that are not sufficiently hygienic.

If we're going to import food from around the world, we need to know something about the conditions under which it is produced. With equivalency authority, FDA could send specialists to evaluate the food safety systems of exporting countries. Like USDA's equivalency evaluations for meat and poultry exporters, this need not be an intrusive investigation. It would consist of a paper review of the exporting country's regulations as well as on-site verification of the exporting country's facilities. For the most part, it would look at the "big picture" to ensure that an exporting country meets basic sanitation standards (such as clean water in its processing plants), has an effective inspection program that includes testing, and possesses the resources to operate its system. It would also ensure that the exporting country's system addresses any pathogens endemic in that country.

Equivalency would not be imposed on exporting countries overnight. It would be a long-term process involving technical assistance to countries that need it. Because implementation would take a long time, Congress should act now to give FDA this authority. Several pending bills, including S. 1707, H.R. 3052, H.R. 3676 and H.R. 4080, would give FDA equivalency authority, but they appear to be languishing.

Finally, and equally important, FDA needs additional funding to perform its responsibilities effectively. While I cannot name a specific dollar figure, it is clear that FDA will need significant additional funding if it is to ensure the equivalency of foreign food safety systems while maintaining an appropriate level of inspection at the border. That is why we are disappointed that FDA will likely only receive a fraction of what the Administration requested to implement the President's Food Safety Initiative.

In conclusion, the FDA and Customs need to improve their procedures for border inspection. However, we hope that Congress will not use this as an excuse for not making more fundamental changes, including giving FDA equivalency authority and much-needed additional funding.

Thank you for this opportunity to share my views. I would be glad to answer any questions you may have.

Senate Permanent Subcommittee
On Investigations
EXHIBIT #1

HIGHLIGHTED INVESTIGATIONS
IMPORTATION OF TAINTED FOODSTUFFS

1. **OFFICE** : Assoc.SAC/NEWARK
CASE OPENED : 01/26/89
CASE STATUS : CLOSED

CASE SUMMARY: This investigation by the Associate SAC/Newark into information received in June 1998 from a convicted smuggler of contaminated foodstuffs regarding alleged bribes paid to FDA Inspectors, through Customhouse brokers, to release imported food shipments led to an undercover investigation resulting in two Customhouse brokers pleading guilty to bribery charges. The brokers then cooperated and led Customs agents to three additional companies bribing FDA Inspectors. The investigation lead to the conviction of presidents of two of the companies, with the third company president dying prior to the indictment being unsealed. In addition, two FDA inspectors that received bribes from these companies pled guilty and cooperated with the government in an undercover capacity. Additional importers and FDA inspectors were subsequently identified as being involved in illegal activity. In all, eleven individuals were either convicted or pled guilty during this investigation.

Specifically, the four FDA Inspectors were sentenced according to their involvement in the scheme as follows: five years three months in prison and fined $10,000; four months in prison and four months house arrest and a fine of $10,000; six months house arrest and five years probation; two hundred hours community service and three years probation.

The two Customhouse brokers were each sentenced to one thousand hours community service, fined $ 10,000, and surrendered their brokers licenses to U.S. Customs.

The import manager of one company was sentenced to three years probation and fined $1,000, while the president and former import manager were each sentenced to five years probation and fined $50,000. Another individual involved was sentenced to eight months in prison and three years probation, while an involved importer was sentenced to five years probation and fined $25,000.

2. **OFFICE** : SAC/LOS ANGELES
CASE OPENED : 01/02/92
CASE STATUS : OPEN

CASE SUMMARY: This was a joint investigation conducted by SAC/Los Angeles and USCS Internal Affairs. Through informant information, it was discovered that a Customs Inspector conspired with principals of a company and other importing firms to smuggle 240 containers of restricted and/or prohibited merchandise (foodstuffs, medicine, etc.)into the U.S. valued at $56 million. A court authorized wiretap and a variety of other investigative techniques were utilized leading to the arrest of the Inspector, who subsequently pled guilty to Smuggling, Bribery and Conspiracy charges and was sentenced to thirty-six months in jail. In addition, $1.6 million in cash which the Inspector received in bribes was seized from the Inspector's home and safe deposit boxes. Two of four others identified in the scheme remain fugitives.

3. **OFFICE** : SAC/TAMPA
CASE OPENED : 12/07/92
CASE STATUS : PENDING
CASE SUMMARY: This was a joint investigation conducted by the SAC/Tampa and the FDA's Office of Criminal Investigation into a scheme by which a large scale importer illegally entered $4.5 million of decomposed shrimp which had been chemically treated to mask the decomposition via false and fraudulent documents to avoid FDA laboratory testing. The shrimp was being sold and consumed throughout the U.S. The company and three of its officers were convicted on a variety of charges relating to the scheme. The company's vice president received a sentence of forty-one months in jail and a $10,000 fine; the general manager received twenty-seven months in jail and a $6,000 fine; the company itself was fined $1 million and ordered to pay court costs and storage costs for the seized merchandise totaling approximately $114,000; a company salesman was sentenced to 2 years probation and a $2,500 fine. Two other individuals remain fugitives.

4. **OFFICE** : SAC/BALTIMORE
CASE OPENED : 07/11/94
CASE STATUS : CLOSED
CASE SUMMARY: This investigation involved a local importer who attempted to reintroduce foodstuffs into the United States after the product was refused entry by FDA inspectors due to a high filth content. The importer had agreed to destroy the shipment, however, it was determined that the importer then attempted to substitute the contaminated products with other foodstuffs and sell the contaminated products to wholesale customers. The company pled guilty to one count of smuggling and was sentenced to one year of probation, a $6,200 fine and $1,600 in restitution to U.S. Customs for storage of the merchandise.

5. **OFFICE** : SAC/MIAMI
CASE OPENED : 05/26/95
CASE STATUS : OPEN (Ongoing)
CASE SUMMARY: The SAC/Miami has been working jointly with the FDA in the investigation of a scheme to import packaged swordfish, fraudulently declared as whitefish in order to avoid FDA testing for methyl mercury. Information about the scheme and its participants was provided by a FDA cooperating witness. The U.S. Attorney's Office for the Southern District of Florida has accepted the case for criminal prosecution. The case involves 188 shipments of swordfish, valued at approximately $6.1 million. The U.S. Attorney's Office and counsel representing the defendants in the case are currently in the process of negotiating a plea agreement.

6. **OFFICE** : SAC/SAN FRANCISCO
CASE OPENED : 12/11/95
CASE STATUS : CLOSED

CASE SUMMARY: In April 1996, the SAC/San Francisco office developed information regarding the illegal importation and smuggling of adulterated foodstuffs and the bribing of public officials. Subsequently, in November 1996, a joint undercover investigation was initiated with the FDA/Office of Criminal Investigations and the Department of Health and Human Services/Office of the Inspector General. The ensuing ten-month investigation disclosed that a licensed Customshouse Broker and two FDA Inspectors had facilitated a scheme to allow adulterated foodstuffs to illegally enter the commerce of the United States from Asia. In September 1997 the undercover operation concluded with the arrest and indictment of the broker, the two FDA inspectors, along with eleven others and one company for their role in the illegal activities, one individual who was indicted is currently a fugitive. In addition, five containers of adulterated foodstuffs valued at approximately $300,000 were seized. The targets had misdescribed the contents of two containers and had attempted to bribe FDA inspectors on the other three containers in order avoid the automatic inspection and laboratory testing by the FDA of the imported foodstuffs. To date of the 14 individuals that were arrested, seven pled guilty and seven are negotiating pleas.

7. **OFFICE** : SAC/LOS ANGELES
CASE OPENED : 01/24/96
CASE STATUS : OPEN

CASE SUMMARY: This was a joint investigation by the SAC/Los Angeles, US Customs Internal Affairs, and the FBI involving a FDA Inspector, USCS OAS Analyst, Customhouse Broker's "Runner" and an importer of foodstuffs. The owners of import company were allegedly bribing the FDA Inspector to allow restricted foodstuffs to enter the U.S. through the Port of Los Angeles. The FDA Inspector and the Customhouse Broker's "Runner" were convicted by jury trial on twelve counts of bribery and seven counts of smuggling. Sentencings pending. The USCS OAS Analyst pled guilty to a misdemeanor violation for disclosing information. Indictment of the import company owners is pending.

8. **OFFICE** : SAC/SAN DIEGO
CASE OPENED : 05/02/96
CASE STATUS : CLOSED

CASE SUMMARY: In March 1996, the inspection of a commercial truck entering the United States from Tijuana, Mexico disclosed fish products from the Orient. The driver declared the merchandise as frozen fish from Mexico. Further examination of the fish by Customs and FDA inspectors revealed it was from shipments which had been refused entry into the United States by the FDA in 1994 due to contamination with salmonella, botulism and filth. The company president pled guilty in federal court for Introduction of Adulterated Food into the Commerce of the United States and was sentenced to one year probation, fifty hours community service, and fine $25.

9. **OFFICE** : SAC/MIAMI
CASE OPENED : 06/14/96
CASE STATUS : OPEN (Ongoing)
CASE SUMMARY: This case involves the investigation and seizure of over 115,000 lbs. of decomposed seafood with a retail value of approximately $538,660. Corroboration of this matter with the FDA led to the shipment being ordered destroyed or exported. The investigation continues in this case due to the fact that the parties, who were ordered to destroy/export the decomposed seafood, attempted to show export of the merchandise by co-mingling it with Mexican snapper fish, resulting in several seizures.

10. **OFFICE** : RAC/NORFOLK
CASE OPENED : 09/19/96
CASE STATUS : OPEN
CASE SUMMARY: Information obtained by the RAC/Norfolk from a confidential informant resulted in the investigation of a company involved in the export and re-packaging of FDA-rejected scallops which were subsequently shipped back to the United States and were fraudulently imported and entered into the commerce of the United States. The U.S. Attorney's office recently presented company with a plea agreement offer with proffer proposal which outlines violations related to wire fraud, customs fraud, false statements, smuggling, money laundering, and marking. The importer has not yet responded to the offer.

11. **OFFICE** : SAC/SAN DIEGO
CASE OPENED : 04/03/96
CASE STATUS : CLOSED
CASE SUMMARY: In February 1997, a simultaneous outbreak of Hepatitis A occurred in school children in Michigan, Maine and Wisconsin, further study revealed the source to be strawberries served as part of the USDA school lunch program. Subsequently, the SAC/San Diego participated with the USDA and the FBI in the investigation of a business in the San Diego area linked to the strawberries, which determined the strawberries were sold to the USDA as products of the United States when they, in fact, were imported from Mexico. Subsequent to the investigation, the sales manager for the company pled guilty to Conspiracy, False Statements, Introduction of Misbranded Foods into Interstate Commerce, and Aiding and Abetting and was sentenced to five years probation, 300 hours community service, and a $300 fine. The president of the company was sentenced to five months in custody followed by five months of home confinement, three years probation, and a fine of $13,698. The company received a fine of $150,000 in restitution to the USDA in addition to an earlier settlement with the government in which the company agreed to pay $1.3 million in civil damages, as well as being financially responsible for the removal and disposal of 916,380 pounds of unconsumed frozen strawberries that were sold to the USDA.

12. **OFFICE** : PORT/SAN FRANCISCO
OP. DATE : 07/21/97
OP. STATUS : CLOSED
OP. SUMMARY : Operation Bad Apple was developed by the Office of Field Operations, San Francisco, as an outgrowth of Operation Shark Fin. Overall, this operation was intended to measure the compliance with import requirements by companies importing foodstuffs into the Port of San Francisco and to take enforcement action against willful and repeat offenders. This operation was conducted with assistance and cooperation of the FDA during July 21, 1997 through August 4, 1997 and was based on selectivity criteria developed to notify the Inspector electronically of a foodstuff import. During the, 1,026 shipments of merchandise matched criteria provided with subsequent examinations resulting in a total of 305 discrepancies and a total of 33 shipments being denied entry into the United States for not meeting FDA requirements. In addition, 13 civil penalties were issued against importers totaling approximately $200,000. No criminal investigations resulted from the operation.

Senate Permanent Subcommittee
On Investigations
EXHIBIT #3

MEMORANDUM

September 8, 1998

TO: PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
MEMBERSHIP LIAISONS

FROM: DON MULLINAX, Chief Investigator
STEPHANIE SMITH, PhD, Investigator
MARY MITSCHOW, Counsel
Permanent Subcommittee on Investigations

VIA: TIMOTHY J. SHEA, Chief Counsel/Staff Director
Permanent Subcommittee on Investigations

RE: PSI HEARING ON FRAUD AND DECEPTION IN THE FOOD IMPORT PROCESS

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I. INTRODUCTION

The Permanent Subcommittee on Investigations (PSI) will hold a hearing on September 10, 1998, at 9:30 a.m. in SD-342. The hearing is entitled "Fraud and Deception in the Food Import Process."

The third PSI food safety hearing will focus on weaknesses in controls over imported food products that enable some importers or their representatives to sell unsafe foods in the United States. The majority of the imported food involved with these unscrupulous practices are not fresh fruit and vegetables but rather frozen seafood and canned or packaged goods. Some of the foodborne diseases associated with these types of imported food, such as Salmonella, could be even more serious to unsuspecting consumers than those associated with fresh fruit and vegetables.

At PSI's first hearing on the safety of food imports, the General Accounting Office (GAO) testified that the FDA has several weaknesses in its controls over imported food products that have enabled some importers or their representatives to sell unsafe food in the United States. GAO testified that FDA's system for automatically detaining suspicious food products, pending testing to confirm their safety, may be easily subverted because the FDA does not maintain control over the testing process. By allowing importers to choose their own laboratories to select samples and perform tests, the FDA opens itself to the possibility of approving the entry of unsafe food products on the basis of falsified test results.[1]

GAO also testified that the FDA does not maintain control over food products before releasing them into U.S. commerce. As a result, some importers have sent food products to grocery stores before the FDA has approved their release. Others have not returned and properly disposed of products that the FDA has conditionally released but called back after testing showed them to be contaminated. Moreover, importers that violate FDA's and Customs' controls are frequently not penalized to deter such actions.

FDA's system for controlling the importation of unsafe foods has a history of circumvention by certain unscrupulous importers. For example, as early as 1992, GAO reported that about 10 importers had repeatedly distributed adulterated shipments contrary to FDA orders. In total, these importers distributed 73 shipments known to have been adulterated.[2] In total, GAO found that about a third of the adulterated shipments that were identified reached the market.[3]

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[1] Because of the short time frame between PSI's first and third hearings as well as the amount of work required to evaluate controls over the laboratory testing process, GAO decided to review and report on the weaknesses in laboratory testing early next year.

[2] Pesticides: Adulterated Imported Foods Are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, September 24, 1992).

[3] Ibid.

A 1997 investigation by Customs confirmed that importers continue to evade food import controls. Recognizing problems with controlling imported food shipments, Customs launched a special operation at the port of San Francisco in 1997, know as Operation Bad Apple. Customs found that of the shipments FDA ordered returned to Customs for destruction or reexport, 40 percent were never redelivered, and for half of those that were redelivered, other products had been substituted for the original contaminated products.[4] Thus, 70 percent of the shipments ordered returned because they were unsafe presumably entered into commerce, contrary to FDA's orders.[5]

GAO concluded at the first PSI hearing that FDA's lack of controls over food shipments selected for inspection leaves its inspection system vulnerable to unscrupulous importers. Without sufficient controls, some importers (i) may falsify laboratory test results on suspect foods to obtain an FDA release, (ii) sell potentially unsafe imported foods before FDA can inspect them, and (iii) sell imported foods that FDA found violative and barred from entry. Further, importers' bonds are an ineffective deterrent against attempts to market contaminated products. As a result, FDA has little assurance that contaminated food shipments are kept off U.S. grocery shelves, and it appears likely that certain importers will continue to circumvent controls over unsafe products with impunity.

It is virtually impossible to determine precisely how much of the food safety problem is attributed to fraud and deception during the import process. As PSI's investigation revealed during the previous hearing highlighting contaminated raspberries from Guatemala, many foodborne illnesses are not reported by Americans who get sick from tainted food. Traceback procedures in many cases are primitive or non-existent. In addition, because of its covert nature, fraud and deception problems are difficult to detect and document. Nevertheless, substantial anecdotal evidence suggests that food shipments imported into the United States by unscrupulous importers contains serious contaminates, such as salmonella, and food not fit for human consumption.

The witnesses called for this hearing will discuss the (i) weaknesses in the food import process that enable entry of unsafe products into the United States and (ii) techniques used by unscrupulous importers or their representatives to circumvent food import laws and regulations. The witnesses include:

Lawrence J. Dyckman, who is GAO's Director of Food and Agriculture Issues, will discuss how importers either sell imported foods before FDA has a chance to inspect them or do not properly dispose of food products that FDA has found to violate U.S. standards. He also will discuss how penalties imposed against importers have not effectively deterred such actions. Mr. Dyckman's testimony is based on Senator Collins' request that GAO perform additional work on the control

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[4] Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable (GAO/RCED-98-103, April 30, 1998).

[5] Ibid.

weaknesses that enable unsafe food products to enter the U.S. commerce that GAO briefly discussed at PSI's hearing on May 14th.

Richard J. Hoglund, who is the Customs Service's Deputy Assistant Commissioner, Office of Investigations, will discuss various techniques used by unscrupulous importers or their representatives to circumvent food import laws and regulations. He will use recent Customs Service criminal cases as well as older cases to illustrate how unscrupulous importers abuse the system. **Philip Metzger**, Director of the Trade Compliance Team, will be available to answer questions about the Customs Service import and inspection process.

If called as a witness, **Mr. Broker**, who is a confidential informant and a former customs broker,[6] will discuss how he has assisted importers, or observed others, in circumventing U.S. Customs and FDA food import procedures.

II. BACKGROUND

A. Food Import System. The FDA and FSIS are the two principal federal agencies responsible for ensuring that the imported shipments of food entering the U.S. are safe. Their systems of inspecting, testing, and approving the release of these food shipments operate independently of each other. To assist these agencies, the U.S. Customs Service provides a number of services, including referring imported shipments for inspection. The Customs Service is the first federal agency that has the opportunity to screen imported food products when they enter the United States. The Customs Service cooperates with FDA and FSIS in carrying out their regulatory roles in food safety.

(1) U.S. Customs Service. Created in 1789, the U.S. Customs Service is one of the federal government's oldest agencies. It is the front-line agency responsible for regulating commerce and detecting contraband at our borders. The Customs Service is responsible for collecting revenue from imports and enforcing various customs and related laws. Customs also processes persons, carriers, cargo, and mail into and out of the United States. In fiscal year 1997, Customs collected about $19 billion in revenues, and processed about 18 million import entries; about 128 million vehicles and trucks; about 706,000 commercial aircraft; about 214,000 vessels; and about 442 million air, land, and sea passengers entering the country.

Customs Service operations are divided into two distinct and separate functional divisions. The "law enforcement" function of the Customs Service is responsible for the enforcement of many

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[6] Customs brokers are private individuals or companies, regulated by the U.S. Customs Service, who aid importers and exporters in moving their merchandise through Customs and providing the proper paper work and payments.

federal criminal laws, including Customs statutes (smuggling), drug laws and other criminal offenses that affect the entry of goods, services or persons into the United States. This division is staffed by sworn law enforcement special agents, similar to the agents that staff ATF, Secret Service, FBI and the DEA.

The other division of Customs is responsible for "inspections." This group conducts all inspections at our borders, and they are responsible for policies and procedures related to the entry of goods into the United States. The inspectors who work in this division have no law enforcement powers and must refer any contraband they discover (drugs, tainted food, etc.) to special agents assigned to the Customs Service's law enforcement division for investigation. This distinction is important since the law enforcement group will be presenting evidence at this hearing about their food import cases, but these witnesses have no responsibility for the food import system, which is administered by the inspections side of the Customs Service.

The Customs Service assists both the FDA and FSIS in carrying out their regulatory role in food safety. Examples of Customs' activities include: checking that imported eggs and egg products are accompanied by a foreign inspection certificate; verifying that imported milk and cream shipments are tagged and accompanied by the required FDA permit; checking that imports of pesticides are accompanied by a Notice of Arrival form which is sent to EPA; and sampling imports upon FDA's request.

The Customs Service has a memorandum of understanding with FDA to: i) establish a working relationship between the two agencies for the cooperative enforcement of Section 801 of the Federal Food Drug and Cosmetic Act; ii) establish uniformity in the exercise of the import-sampling and refusal authority; and ii) delegate authority to certain FDA officers to collect samples and issue Notices of Sampling and Notices of Refusal of Admission on behalf of the District Director of Customs.

(2) FDA Import System. To ensure that FDA is notified of all food products under its jurisdiction that are imported into the United States, an importer must file an import notice along with certain shipping information and, for shipments valued over $1,250, a bond to cover the goods for release with the Customs Service within five days of the shipment's arrival at a U.S. port of entry. The import documents or electronic entry data identify the type of food product, the importer, foreign manufacturer, and country of origin. The bond, which covers potential duties, taxes, and penalties, may allow the importer to retain control of the shipment until FDA decides to inspect samples, test, or release it.[7] If an importer fails to make an import shipment available for FDA's

[7] Importers generally obtain continuous bonds that provide coverage for multiple shipments over a specified time period. The amount of a continuous bond is based primarily on a percentage of duties paid in the previous year. Importers can also purchase bonds for single shipments (single-entry bonds) in an amount three times the declared value of the shipment. The declared value is based on the cost of the goods to the importer.

inspection, fails to recondition, or fails to destroy or re-export the shipment, as directed by FDA, Customs may collect penalties against all or part of the bond value.

To assist FDA in reviewing all shipments, the Customs Service's computer system uses the information provided by the importer and FDA-developed screening rates to determine which shipments to automatically release into domestic commerce and which shipments to review further. FDA sets the screening rates using several sources of information, such as the annual work plan, type of product, and past violations of products or shippers. Most shipments that are believed to pose minimal safety risks, such as candy and dried pasta products, are frequently released automatically because they have, historically, low violation rates. FDA releases these shipments a few minutes after the importer enters the information. Other shipments, such as some seafood and low acid canned foods, are less frequently or never released automatically, because they pose greater potential health risks.

For products not automatically released, Customs forwards shipment information to FDA for further review, through FDA's automated screening system, known as the Operational and Administrative System for Import Support (OASIS). This system was pilot-tested in 1992 and installed at all FDA's district offices by October 1997. Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to the Customs Service. Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed -- such as the databases with information on products to be automatically detained and registration numbers for foreign firms -- to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most shipments not requiring further review within three hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

FDA inspects or conducts laboratory analyses on a small percentage --currently less than two percent annually -- of all types of imported food shipments under its jurisdiction. Inspections may occur at ports of entry, at warehouses or other business establishments. If FDA decides to test an imported food shipment, a FDA inspector collects a sample from the shipment and sends it to a FDA laboratory for analysis. FDA maintains a record of all laboratory test results in its Laboratory Management System database. For samples found to comply with U.S. standards, FDA notifies Customs and the importer that the shipment can be released. For samples found to violate these standards, FDA notifies Customs and the importer that the shipment is refused entry into the United States. Importers generally have three options for handling shipments refused entry. If FDA concurs, importers can (i) recondition the shipment; (ii) destroy it; or (iii) re-export the goods. Whatever option the importer chooses, Customs Service officials are required to supervise proper disposition of the refused shipment.

(3) FSIS Import System. Before foreign firms can export meat and poultry to the United States, FSIS must have determined that the exporting country has a food safety system for these products that is equivalent to the U.S. system. Unlike FDA, FSIS inspectors visually check every

imported shipment of foods under their jurisdiction for correct documentation, transportation damage, and correct labeling at FSIS-approved import inspection stations.[8] FSIS conducts more intensive inspections and tests on a portion of the imported shipments -- about 20 percent in 1997 -- to verify the effectiveness of the foreign food safety system. FSIS calls this process "reinspection" because the product has already passed inspection by the exporting countries' equivalent inspection system.

Importers of FSIS-regulated products, like importers of FDA-regulated products, must file an import notice and file a bond with the Customs Service within five days of the date that a shipment arrives at a port of entry to cover their goods for release. Unlike FDA, however, importers must hold shipments at FSIS-registered warehouses for FSIS' inspection until these shipments are released into the domestic market or refused entry. In the case of FSIS-regulated products, unlike FDA regulations, the importer does not retain control over the food shipment pending government inspection.

FSIS inspectors enter the information provided by importers -- such as country of origin, foreign manufacturer, exporting country's health certification, and type of product -- into a centralized computer system. This computer system, which was installed in 1979, is known as the Automated Import Information System (AIIS). The system scans the information it contains to determine if the country, plant, and product are eligible for import into the United States and whether the shipment will be allowed entry with only a visual check or be subjected to more intensive inspections and tests.

The AIIS system uses computer-assigned screening procedures and individual plants' performance histories to target shipments for more intensive inspection and testing. Under the system, one violation on the previous shipment of a particular product, such as boneless beef, triggers more intensive inspection and testing for the same type product from the same foreign firm until FSIS has found at least 10 successive shipments that are free of violations and meet U.S. standards. Violations that generate more intensive inspections include food products that contain chemical residues or bone fragments, have misidentified products, or have microbial contamination. If the imported products do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food. Unlike FSIS, the FDA does not mark adulterated products with "U.S. Refused Entry." According to FDA officials, the FDA does not have explicit statutory authority to place this marking on refused shipments. FSIS uses information on refused shipments to plan inspections in foreign countries.

(4) Customs Brokers. Customs brokers are private individuals or companies, regulated by the U.S. Customs Service, who aid importers and exporters in moving their merchandise through Customs. A customs broker's activities include:

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[8] FSIS is responsible for processing just 118,000 food entries per year while the FDA has jurisdiction over approximately 2.7 million food entries into the United States.

- Preparing and filing entry documentation with the U.S. Customs Service for goods entering the United States;

- Reviewing the classification, duty rate, and assigned value of the imports. If there is a problem or a discrepancy, they pursue the appropriate administrative remedy with the Customs Service;

- Depositing the correct duty payment with the Customs Service on behalf of the importer (though the broker actually pays the duty, the importer is ultimately responsible for payment);

- Securing release of the goods from the Customs Service;

- Obtaining a bonded warehouse if desired by the importer; and
- Arranging delivery of the goods to the importer's warehouse or plant.

Customs brokers charge a fee for these services (usually between $60 and $125 per entry), but no person may conduct these activities unless that person holds a valid customs broker's license which is issued by the Secretary of the Treasury.

To obtain a broker license, an applicant must be a U.S. citizen of good moral character and be at least 21 years of age. The applicant must pass an examination (a score of 75 percent or higher) that consists of 75 to 100 multiple-choice questions. Once an applicant passes the examination, the Customs Service conducts a background investigation which includes character references, credit references, and arrest records. Each licensed broker is required to submit a report to the Treasury Secretary every three years to show whether the broker is actively engaged in business and, if so, the report must contain the location where business is being conducted.

(5) Importers. An importer can be an individual, group of individual or a business. The U.S. Customs Service does not require an importer to have a license or permit. Depending on the commodity, other agencies may require a permit, license or other certification. All merchandise coming into the United States must clear customs and is subject to a customs duty unless specifically exempted by law from this duty. Clearance involves a number of steps – entry, inspection, appraisal, classification, and liquidation.

To make or file a customs entry, several documents are required: (i) a bill of lading, airway bill, or carriers's certificate as evidence of the consignee's right to make entry; (ii) a commercial invoice, obtained from the seller, which shows the value and description of the merchandise; (iii) entry manifest (Customs Form 7533) or Entry/Immediate Delivery (Customs Form 3461); and (iv) packing lists and other documents, if necessary, to determine whether the merchandise may be admitted. When the entry is filed, the importer indicates the tariff classification and pays any estimated duty and processing fee. A surety bond containing various conditions, including a provision for paying any increased duty that may be later found to be due, may also be required. The

importer is authorized to prepare and file entry documents as well as perform any other activities required to gain entry of the product into the United States or the importer may contract with a customs broker to handle these duties.

(6) Bonded Warehouse. Imported food shipments are normally transported from the port to the importer's warehouse or to a bonded warehouse. Duties and processing fees are not paid on shipments placed in bonded warehouses until the goods are released or withdrawn for consumption. Importers may request that the goods be placed in a bonded warehouse in order to repackage, sort, or clean the goods or Customs officials may direct that the goods be delivered to a bonded warehouse in order for Customs officials to conduct an inspection. The importer is responsible for paying any costs associated with unloading and storing the goods; however, bonded warehouses are operated independently of importers.

The Secretary of the Treasury designates facilities as bonded warehouses. These facilities are privately-owned third party secure facilities that are used solely for the storage of imported goods. A customs officer and proprietor have joint custody of all the goods stored in the warehouse. Any required labor associated with the stored goods is performed by the owner or proprietor of the warehouse under supervision of the customs officer. Bonded warehouses give the government more control over the imported goods since an independent third party and not the importer has physical control over the shipments until they are inspected and released by the Customs Service.

B. General Accounting Office Reports. The GAO identified weaknesses in the food import process as early as June 1979. The following paragraphs contain selected excerpts from three GAO reports, and they illustrate the fact that there are systemic and long-standing problems with the food import process in this country.

In June 1979, GAO reported that "[h]alf of the imported food that the Food and Drug Administration found to be adulterated during a 15-month period was marketed without penalty to importers and consumed by an unsuspecting American public."[9] GAO further reported that "[i]mporters are not penalized for marketing adulterated foods provided a reasonable attempt was made to recall the food. However, even importers with histories of repeated violations are not penalized and their imports are seldom detained pending analysis."[10]

In September 1986, GAO reported that "FDA's policy requires importers to maintain all sampled shipments intact until the agency determines that the product is free of illegal pesticide residues. In practice, however, FDA permits importers to release the majority of sampled shipments to U.S. markets to allow consumers to receive fresh fruits and vegetables before they spoil. FDA

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[9] Better Regulation of Pesticide Exports and Pesticide Residues in Imported Food is Essential (CED-79-43, June 22, 1979).

[10] Ibid.

is to notify Customs if illegal residues are later found in the sample and Customs in turn is to notify the importer to return the shipment. If the shipment is not returned, Customs is required to assess liquidated damages unless FDA recommends otherwise. FDA usually recommends against assessing damages in those cases where it has not found previous violations by the grower during the current growing season."[11]

During the 1986 review, GAO found that of 164 adulterated samples reviewed, 73 were not recovered and were presumed to have been consumed by the public. FDA recommended against damages in 52 of the 73 cases. In addition, GAO was able to document only eight cases where importers were assessed damages. Damages in six cases had not been collected a year after being assessed. Thus, about 45 percent of the adulterated shipments were reaching consumers with few importers paying damages. The irony is that the importer that recovers and disposes of the adulterated shipment incurs an economic loss while those that do not, incur no economic loss.

In September 1992, GAO reported that "[e]ven though importers are required to return adulterated foods to Customs for supervised disposal, in the four FDA districts included in our review, one-third of the adulterated shipments were not returned and were presumably sold in commerce."[12] GAO found that during fiscal years 1988-90, in four locations reviewed, importers did not properly dispose of 336 of the 989 imported shipments that FDA found to be adulterated with pesticides. While GAO could not document that the 336 adulterated shipments actually reached U.S. consumers, both Customs and FDA records confirmed that importers were selling adulterated food into U.S. food distribution channels. Of the 336 adulterated shipments, GAO found that 62 were distributed as a result of errors by FDA or Customs. According to the records, the rest were illegally distributed without a FDA release. In 51 cases, importers claimed to have exported or destroyed the shipment but could not provide the required Customs verification of disposal.

III. WITNESSES

A. Lawrence J. Dyckman, GAO. Mr. Dyckman's testimony is based on Senator Collins' request that GAO perform additional work on the control weaknesses that enable unsafe food products to enter the U.S. commerce that GAO briefly discussed at PSI's hearing on May 14th. He will describe how importers either sell imported foods before FDA has had a chance to inspect them or do not properly dispose of food products that FDA has found to violate U.S. standards and how penalties against importers have not effectively deterred such actions. Mr. Dyckman's testimony will be based on staff visits to ports of entry in Los Angeles and San Francisco, California; Seattle

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[11] PESTICIDES: Better Sampling and Enforcement Needed on Imported Food (GAO/RCED-86-219, September 26, 1986).

[12] PESTICIDES: Adulterated Imported Foods are Reaching U.S. Grocery Shelves (GAO/RCED-92-205, September 24, 1992).

and Blaine, Washington; Laredo and Pharr, Texas; Miami, Florida; and New York, New York. Finally, he will provide some options (not recommendations or endorsements) for Congress to consider for improving the identified weaknesses.

B. Richard J. Hoglund, U.S. Customs Service. Mr. Hoglund is the Deputy Assistant Commissioner, Office of Investigations. He will describe the techniques used by unscrupulous importers or their representatives to circumvent food import laws and regulations. His testimony will include descriptions of techniques discovered during undercover or special operations conducted at U.S. ports of entry. Mr. Hoglund's testimony will also show how the weaknesses identified by GAO encourages fraud and deception to occur. Although only one witness from the Customs Service will present an oral statement, other Customs officials will be available for questions, including officials from the inspections side of Customs (the group responsible for administering the food import process). Mr. Hoglund, responsible for Customs Service law enforcement functions, will not be able to answer questions about the import process; so we asked the Customs Service to provide an official responsible for inspections in order to give Members an opportunity to raise issues about the import polices and processes. This Customs official will be **Philip Metzger**, who is Director of the Trade Compliance Team in the Office of Field Operations

C. Mr. Broker. If called as a witness, the confidential informant will describe how he has assisted importers, or observed others, in circumventing U.S. Customs and FDA food import procedures. The confidential informant is a former customs broker. The former broker has pleaded guilty in federal court to a felony (making false statements in conjunction with exporting stolen vehicles) and is scheduled to be sentenced on September 29, 1998. The informant was a customs brokers for about 20 years in the San Francisco area.

The informant will describe how importers use port-shopping, container-switching and "banking" schemes to get suspect food products into the United States. He also will discuss how the FDA's automatic detention program is not a deterrent for some importers. In fact, he will testify that some importers prefer having their food products on the automatic detention listing because this allows importers complete control over their products. In contrast to regular import procedures, the FDA allows the importers, if they are on the automatic detention list, to choose the laboratory to perform any required testing. Finally, the former broker will describe flaws in FDA's sampling process, how some importers falsify laboratory test results, and the process used to fake the destruction of products that FDA has refused entry into the United States.

IV. HEARING THEMES

The third hearing on the safety of food imports will focus on how fraud and deception in the food import process creates potential health risks to U.S. consumers. Fraud and criminal activity in general only occurs when two elements converge: motive and opportunity. Motive for criminal activity in most cases is the age-old vice of greed. A review of cases indicates that greater profits and the low risk of apprehension provide the motive for unscrupulous importers to ship unsafe food

into this country. Opportunity, with respect to fraud in the food import process, is the ability of unscrupulous importers to use existing procedures to facilitate crime. This hearing will focus on how the current system presents less than honest importers with the opportunity to defraud and deceive in order to import unsafe food into the United States.

GAO has identified, and Customs Service criminal cases have confirmed, that the current system gives criminal elements the opportunity to evade import controls and bring tainted food into the country. And the impact is not merely monetary as it is with most fraud-related crime. Here, the impact is far greater, affecting the health and safety of all Americans who consume food imported into the country.

The specific themes for the hearing are:

- What control weaknesses in the food import process enable entry of unsafe products into the United States?
- What techniques are used by unscrupulous importers or their representatives to circumvent food import laws and regulations?
- What are some possible options to improve the controls over food imports?

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Senate Permanent Subcommittee on Investigations

EXHIBIT #_1_

MEMORANDUM

September 22, 1998

TO: PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
MEMBERSHIP LIAISONS

FROM: DON MULLINAX, Chief Investigator
STEPHANIE SMITH, PhD, Investigator
MARY MITSCHOW, Counsel
Permanent Subcommittee on Investigations

VIA: TIMOTHY J. SHEA, Chief Counsel/Staff Director
Permanent Subcommittee on Investigations

RE: PSI HEARING -- IMPROVING THE SAFETY OF FOOD IMPORTS

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I. INTRODUCTION

The Permanent Subcommittee on Investigations (PSI) will hold two days of hearings on September 24 and 25, 1998, at 9:30 a.m. in SD-342. The hearing is entitled "Improving the Safety of Food Imports."

The two-day hearing is the fourth in a series focusing on the safety of food imports. It will call on various stakeholders from the public and private sectors to provide recommendations for improving the safety of imported food. The hearing will focus, in part, on addressing the weaknesses in the food import process identified by the General Accounting Office (GAO) in its April 1998 report to the Subcommittee entitled "Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable" and again in testimony provided during the third hearing entitled "Weak and Inconsistently Applied Controls Allow Unsafe Imported Food to Enter U.S. Commerce."

The safety of our food supply is something that we take for granted. Whether we shop at a corner convenience store or a deluxe supermarket, we expect the quality of our food products to be consistently high. We place food products and produce into our grocery baskets, assuming that the food we bring home to our families is tasty, wholesome, and, most of all, safe. In recent years, the way we grow and transport fruit and vegetables, process foods, consume, and cook have been transformed. We eat out more, we want convenience, novelty, year-round availability, and cheapness. For their part, food producers want to increase efficiency and shelf-life and to maximize profits.

American consumers spend about $617 billion a year on food.[1] The federal government spends over $1 billion a year to protect the safety of the nation's food supply.[2] State governments and industry spend unknown additional amounts. Foodborne illnesses, however, still occur, and recent outbreaks have raised questions about the safety of the U.S. food supply.

While most experts agree that the U.S. food supply is among the safest in the world, as many as 81 million cases of foodborne illness and as many as 9,100 related deaths occur each year in the United States.[3] The exact number of foodborne illnesses, however, cannot be accurately stated because there are not adequate processes and procedures in place to identify and track food products from the table back to the farm.

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[1] CRS, 1998. Food Safety Agencies and Authorities: A Primer. 98-91 ENR, p. 1.

[2] GAO, 1990. Food Safety and Quality: Who Does What in the Federal Government. RCED-91-19A&B. This includes programs related to both domestic and imported food.

[3] GAO, 1996. Food Safety: Information on Foodborne Illness. RCED-96-96.

Public health experts believe the majority of foodborne illness cases are not reported because: i) the initial symptoms of most foodborne illnesses are not severe enough to warrant medical attention; ii) medical facilities or state health authorities do not report the cases; or iii) illnesses are simply not recognized as having been foodborne. Recent estimates suggest that the cost of foodborne illness due to medical treatment and lost productivity ranges from $6.6 billion to $37.1 billion a year.[4]

More pathogenic organisms are showing up on fresh fruit and vegetables, of which consumers are eating increasing quantities for their nutritional benefits – the National Cancer Institute advocates eating five servings of fruit and vegetables a day. As an example, in 1997, over 200 children and teachers in Michigan developed hepatitis after eating frozen strawberries that were imported from Mexico.[5] Those berries were illegally provided to the school lunch program, which requires food to be produced in the United States. According to Maine's state epidemiologist, Dr. Kathleen Gensheimer, these imported strawberries contributed to at least 29 laboratory-confirmed cases of hepatitis A in Maine.[6] In another example, over 2,000 people were infected with *Cyclospora* in 1996 and 1997 from eating raspberries from Guatemala,[7] making this the largest outbreak of foodborne disease in recent years. These tainted raspberries even made their way to Maine, as well as to seven other states whose Senators are Members of this Subcommittee. As consumers become aware of the serious consequences of these illnesses and as illnesses are linked to a growing variety of foods, consumers are looking to the government to further protect the food supply.

During the 1990's, at least eleven other outbreaks have been linked to imported foods. In the words of Dr. Michael Osterholm, Minnesota's state epidemiologist, for example, "[o]ne no longer needs to leave home to contract traveler's diarrhea caused by an exotic agent."[8] Because a significant amount of food is imported into this country, concerns about food safety extend beyond our borders. In 1997, about 2.7 million imported shipments of food were received in the United States.[9] The Food and Drug Administration (FDA), however, inspected only 1.7 percent of these shipments.[10] In January 1998, one typical grocery store in America displayed for sale fruit and

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[4] GAO/RCED 98-103, p. 2.

[5] Hepatitis Control Report, Spring, 1997.

[6] State of Maine, Dept. of Human Services, 1997. Hepatitis A Investigation Completed. Maine Epi-gram, 10/97.

[7] CDC, Fact Sheet, Outbreaks of Cyclosporiasis in the United States, Jan. 98.

[8] Sandra G. Boodman, The Washington Post, 7-8-97, "Forbidding Fruit: How Safe is Our Produce?"

[9] GAO/RCED-98-103, p. 25.

[10] Ibid, p. 26.

vegetables from 28 countries: Costa Rica, Honduras, Colombia, Dominican Republic, Chile, New Zealand, Argentina, Taiwan, Spain, Brazil, Indonesia, Holland, Guatemala, Canada, South Africa, Panama, Mexico, Italy, Belize, Belgium, Korea, Japan, China, Israel, Portugal, France, Ecuador, and Tahiti.

Dr. David Kessler, former FDA Commissioner, has stated that while "[w]e built a system back 100 years ago that served us very well for a world within our borders . . . [w]e didn't build a system for the global marketplace." Similarly, Caroline Smith DeWaal of the Center for Science in the Public Interest, has stated that "What we do know is that we've got a lot of fruits and vegetables imported from countries where we're warned not to eat them [raw] or to drink the water . . . . [T]he question is, why is it safe to eat it when it's imported?"

The witnesses called for these hearings will provide suggestions for improving the safety of imported food. The witnesses include Members of Congress, representatives from Executive Branch Agencies (U.S. Customs Service, Food and Drug Administration, and Food Safety and Inspection Service), and representatives from the private sector, including several industry and consumer groups. These witnesses are highlighted in Section V of this memorandum.

III. BACKGROUND

A. Imported Foods in U.S. Food Supply. A growing percentage of the United States food supply is imported. Agricultural imports, such as meat, poultry, dairy, fruits, vegetables, and coffee increased by 47 percent between 1990 and 1996 ($22.8 billion in 1990 to $33.6 billion in 1996).[11] The sheer volume of these imports, along with the difficulty of ensuring that they are safe, adds to the risk of foodborne illnesses. As the following chart shows, the import share of some commonly consumed foods is increasing.[12]

Import Item	Percentage of Total U.S. Consumption Provided by Imports				Percent Change, 1980-1995
	1980	1985	1990	1995	
Fish and shellfish	45.3	53.8	56.3	55.3	22.1
Fresh fruits	24.2	28.0	30.7	33.3	37.6
Fresh vegetables	7.6	8.9	8.4	11.7	53.9
Tomatoes for processing	1.4	7.0	5.7	3.5	150.0
Broccoli for processing	9.1	22.2	57.8	84.9	833.0

[11] USDA, 1990 and 1996. Foreign Agriculture Trade of U.S.

[12] GAO/RCED-98-103, p. 13.

Between 1990 and 1996, the dollar value of imported fruit and vegetables into the United States increased by 48 percent (from $4.8 billion to $7.2 billion).[13] At least 90 different countries import fruit and vegetables to the United States. Some of the countries and associated dollar amounts with the largest increases were:

Imports of Fruit & Vegetables
(in millions of dollars)

	1990	1996	Percent Increase
China	75	205	173
Canada	277	702	153
Costa Rica	252	462	83
Mexico	1,300	2,100	62
Guatemala	153	229	50

As the percentage of imported foods consumed in the U.S. increases, the importance of ensuring that these foods are safe increases as well. Foods can become contaminated at any point in the food chain, from farm to table. In the case of imported foods, part of this chain exists outside the U.S. Ensuring food safety, therefore, cannot be achieved by focusing on domestic points or products exclusively.

B. Risks Posed by Imported Foods. Risks that may be or may not be unique to imports are posed by foods containing pathogenic microorganisms to which the American consumer may not be immune; or by levels of contaminants, pesticide, or veterinary drug residues in excess of U.S. tolerances. Risk is a measure of the probability that a substance could lead to an adverse effect.[14] Risk assessment is used to estimate the likelihood and severity of harm to human health from exposure to a hazard. A hazard is the intrinsic property of a substance that could cause an adverse effect.[15] Risk assessment considers source of hazard and characteristics of exposure, including duration, dose, and dose response. The components of risk analysis are risk assessment, risk management, and risk communication.

(1) Types of Foodborne Hazards. A foodborne illness results from ingestion of a contaminated food. If the hazard is a disease-causing microorganism, the illness is an infection; if the hazard is a chemical, the illness is called an intoxication. A chemical hazard may be either man-

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[13] Ibid.

[14] Smith, M. 1997. Basic requirements of risk evaluation and standard setting. In Food Safety and Toxicity. J. de Vries, ed. CRC Press, Boca Raton, FL.

[15] Ibid.

made or naturally-occurring including residues of veterinary drugs and agricultural chemicals as well as toxins produced by plants, mold and bacteria. Physical hazards, such as broken glass or metal fragments, may also pose a risk. The resultant conditions induced by a hazard may be acute and/or chronic. Of all hazards associated with foods, the microbiological types pose the greatest risk, accounting for more than 90 percent of confirmed foodborne outbreaks and cases.[16]

Foodborne pathogens may be classified as viruses, bacteria, or parasites, including protozoa and worms, and are generally referred to by genus and species, excluding viruses.[17] The significance of and potential hazard associated with a given pathogen depends on the: i) type of food; ii) number of microbes present; iii) amount of food ingested; iv) treatment before consumption; and v) consumer susceptibility.[18]

Many raw foods contain low levels of certain pathogens. Clearly, they can cause disease if ingested raw, improperly cooked, or otherwise mishandled. Poor personal hygiene also increases the risk. Children, elderly, and individuals immunocompromised as a result of transplant surgery, chemotherapy, or AIDS are generally more susceptible to disease. As part of the national public education campaign to reduce the risk of foodborne illness, entitled "Fight Bac!," the Public Health Service has identified 10 microorganisms as being the largest contributors to foodborne illness, either because of the severity of the sickness or the number of cases of illness they cause.

According to the U.S. Public Health Service, the leading pathogens causing foodborne illnesses in the United States are: *Campylobacter jejuni, Clostridium perfringens, Escherichia coli* O157:H7, *Listeria monocytogenes, Salmonella* spp., *Staphylococcus aureus, Shigella, Toxoplasma gondii, Vibrio vulnificus*, and *Yersinia enterocolitica*.

- *C. jejuni* is a major bacterial cause of diarrhea and may be the most common factor leading to Guillain-Barre syndrome, one of the leading causes of paralysis from disease. It may be found on raw and undercooked meat and poultry and in raw milk and untreated water.

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[16] Council for Agricultural Science and Technology (CAST). 1994. Foodborne Pathogens: Risks and Consequences, CAST Task Force Report No. 122.

[17] Microorganisms are correctly referred to by their genus and species name, eg. *Listeria monocytogenes*. After the first appearance, the name may be shortened by using only the first letter of the genus followed by the full species name. An entire genus may be referred to nonspecifically, eg. *Salmonella*. In some cases, when an organism has special features, it is necessary to specify the genus, species, and serotype, eg. *Escherichia coli* O157:H7 or *E. coli* O157:H7. Viruses are not living organisms and are named otherwise.

[18] CAST Report No. 122.

- *C. perfringens* produces a sudden onset of colic followed by diarrhea and nausea. It has been associated with improper heating of prepared foods, including roast beef, turkey, pork, chicken, and ground beef.

- *E. coli* O157:H7 can produce a toxin which may cause hemolytic uremic syndrome, characterized by kidney failure, hemorrhagic colitis, and death. It has been associated with meat, particularly undercooked or raw hamburger, raw milk and produce.

- *L. monocytogenes* can cause stillbirths and miscarriages in pregnant women and meningitis. It has been associated with improperly processed dairy products, including soft cheeses. It may also be found in raw and undercooked meat, in poultry and seafood, and in produce.

- *Salmonella* spp. causes reactive arthritis, serious infections, and death. It has been associated with raw and undercooked eggs, poultry, and meat. It may also be found in dairy products, seafood, and fruits and vegetables.

- *S. aureus* causes staph infection. It may be found in cooked foods high in protein, such as cooked ham, salads, bakery products, dairy products.

- *Shigella* causes dysentery. It may be found in salads, milk and dairy products, and produce.

- *T. gondii* is a parasite that causes a severe disease that can produce central nervous system disorders. It may be found in meat, primarily pork.

- *V. vulnificus* causes a syndrome known as primary septicemia. It may be found in raw or undercooked seafood.

- *Y. enterocolitica* causes a disease characterized by diarrhea and/or vomiting. It may be found in pork, dairy products, and produce.

While these are the 10 leading pathogens, at least 30 pathogens are commonly associated with foodborne illness.[19] According to the Center for Disease Control and Prevention (CDC), of the 18 outbreaks of foodborne illness linked to imported food that occurred between 1983 and 1997, nine were associated with microorganisms on the "top ten" list.[20] The other implicated microorganisms were: *Cyclospora, E. coli* O153:H45, *E. coli* O27:H20, the Hepatitis A virus, and

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[19] Partnership for Food Safety Education, 1997. Foodborne Illness: A Constant Challenge.

[20] GAO/RCED-98-103, p. 47.

an unidentified Norwalk-like agent. One outbreak was attributed to scombroid (histamine) poisoning. Eight of the outbreaks involved produce, including raspberries, strawberries, alfalfa sprouts, green onions, cantaloupes, and lettuce.

While awareness of less common hazards is increasing, contaminated imported foods often challenge our health care providers and our infectious disease surveillance efforts. Because foodborne and waterborne infections that emerge abroad affect U.S. as well as foreign populations, international efforts are often needed. As Robert Tauxe of the CDC observed with regard to the increasing quantities of food coming from the developing world, "... the people who pick our green onions and strawberries and pack them in boxes and ship them to us so that we can eat them, are food handlers -- our food handlers. Even if we could have a wand and make our food sterile and completely safe, as we import more and more the problems of the developing world are going to be our problems. Those are the hands that feed you, and it might actually matter whether they are washed or not or whether they have a latrine. If we are interested in the safety of our food, then we have to be interested in the living conditions of the people who handle it."

Improving the microbial safety of drinking water and food production in developing countries is critical to decreasing morbidity and mortality there and to ensuring the safety of the increasing amounts of food imported to the U.S. from such countries.[21] As part of its effort to address emerging infectious disease threats, the CDC developed "A Prevention Strategy for the United States." One of the objectives of the plan is to strengthen and integrate programs to monitor and prevent emerging infections associated with food and water, new food processing technologies, and environmental sources. Coordination between the CDC and regulatory agencies is essential because surveillance and investigation of human disease can identify the need for new regulations as well as evaluate the effectiveness of existing ones.

(2) Increasing Risks. Public health and food safety officials believe the risk of foodborne illness is increasing due to changes in population demographics, pathogenic microorganisms, and the food supply itself. Simply put, consumers and their environments are changing. Three populations at high risk are young children, the elderly and the immunocompromised. Group settings, such as day care centers and nursing homes also increase the likelihood of person-to-person pathogen transmission.

The microorganisms causing foodborne illness are also changing: benign organisms are becoming virulent; pathogenic organisms are crossing species barriers; and new organisms are emerging. One example of an "old friend" turned violent enemy is *Escherichia coli*. Genetic changes in this well-characterized microorganism of the human gut have created the new serotype, O157:H7, known to be a killer. Well-known animal pathogens, such as *Listeria monocytogenes* and *Yersinia enterocolitica*, are now known to cause disease in humans as well. Some foodborne

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[21] CDC, 1994. Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States. HHS, Public Health Service, Atlanta, GA.

pathogens have only recently been identified, such as *Cyclospora*. The first known human cases of cyclosporiasis were reported in the medical literature in 1979.

The food supply is also changing both in the way food is made and from where food comes. Centralized food production facilities and extensive distribution systems mean a single contaminated product may affect a large number of people in many areas. As consumption of imported foods increases, so does the opportunity for exposure to diseases previously unknown to United States consumers, including diseases eradicated in the United States such as cholera. For example, incidence of *Cyclospora* in the United States was virtually unknown prior to 1996. Yet between May and August 1996, the CDC had more than 1,400 reported cases.[22] In the past, cyclosporiasis was typically found in people who lived or traveled in developing countries.

Contaminated food and drink are common sources for the introduction of infection into the body. Many of United States food imports, however, come from developing countries where sanitation and hygiene are often inadequate and safe water is not available. High-risk regions in this respect include most of the developing countries of Latin America, Africa, the Middle East, and Asia. Travelers to these areas are advised to avoid salads, uncooked vegetables, unpasteurized milk, and milk products, yet there are no restrictions for exportation of the same items to the United States. CDC officials have warned that improving the microbiological safety of drinking water and food production overseas is crucial to insure the safety of the increasing amounts of food imported to the United States.

As Nicols Fox recently wrote: "Once our cookbooks and nutrition guides told us to eat the skins of vegetables because that was where the vitamins were found in abundance; now we are told to peel and throw them away because that is where the poisons are found, the ones we hope have not made it inside."[23]

C. Federal Authorities and Responsibilities. At least 12 different federal agencies share authority and responsibilities with regard to imported food products. Not all of these agencies, however, have a food safety mission. This fragmentation of federal responsibility has required extensive efforts by federal regulatory agencies to coordinate their activities. As an example, there are at least 51 different written interagency agreements directed at avoiding wasteful duplication of effort, preventing gaps in coverage, and avoiding conflicting actions.[24]

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[22] Herwaldt BL, Ackers M-L, and the Cyclospora Working Group. An outbreak in 1996 of cyclosporiasis associated with imported raspberries. N Engl J Med 1997; 336:1548-56.

[23] Fox, Nicols. 1997. Spoiled: The Dangerous Truth About a Food Chain Gone Haywire. Basic Books, N.Y, N.Y.

[24] GAO/RCED-91-19A, p.5.

Four federal agencies have specific food safety jurisdictional responsibilities – the Food and Drug Administration (FDA), the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), the Environmental Protection Agency (EPA), and the CDC. Their jurisdictions often depend on the type of food, the way the food is processed, or what type of contaminant could be found in a particular food. The regulatory responsibilities of these agencies cover the entire food chain from farm to table. At times their jurisdictions overlap. Critics have charged that this duplication of effort is wasting taxpayers money and does not allow efforts to focus where the risk of adulteration and contamination is the greatest.

Former FDA Commissioner David Kessler during a recent speech at a forum on food irradiation stated, "We lurch from one outbreak to the next in a haphazard, sometimes inconsistent fashion . . . Sooner or later, the public will insist that the federal government speak with one voice."

The following federal agencies regulate the safety and/or importation of food products into the United States.

(1) The Food and Drug Administration. The FDA is responsible for ensuring that domestic and imported food products -- except for most meats and poultry -- are safe, sanitary, nutritious, wholesome, and are honestly labeled. The FDA has jurisdiction over meats from animals or birds that are not under the regulatory jurisdiction of FSIS. These include rabbit, deer, moose, buffalo, quail, or ratites (ostriches, emu and rheas) that have not been submitted for inspection under a voluntary FSIS ratite inspection program. The FDA shares responsibility for the safety of eggs with FSIS. The FDA has jurisdiction over establishments that sell or serve eggs or use them as an ingredient in their products. The FDA also is the primary federal agency responsible for ensuring that all domestic and imported seafood products, including those from aquaculture, do not endanger public health (FDA spends about $42 million annually on seafood safety). The agency's budget devoted annually to all food safety regulation is approximately $213 million. The primary statutes governing FDA's activities are the Federal Food, Drug, and Cosmetic Act, as amended; the Public Health Service Act, as amended; and the Egg Products Inspection Act, as amended.

FDA's inspection force numbers roughly 800 and is located in field offices in 49 states, the District of Columbia, and Puerto Rico. About 53,000 food establishments are subject to periodic FDA inspection for compliance with regulations in the areas of sanitation, ingredient labeling, nutrition labeling, good manufacturing practices, low-acid canned foods, acidified foods, and food standards. Some FDA inspectors are located at airports, seaports, and other locations where the FDA carries out inspection of imported foods. Twenty-nine district offices with affiliated laboratories administer the day-to-day operations of the field offices. The FDA regulates food establishments' safety practices by relying on food companies' self-interest in producing safe products and by working with the industry to improve production practices. According to GAO, unannounced compliance inspections of individual establishments by FDA officials now occur roughly once every 10 years. The FDA relies on notifications from within the industry, or from other federal or state inspection personnel, as well as other sources, to alert it to situations calling for increased inspection.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for (i) conducting and supporting food safety research, (ii) developing and overseeing enforcement of food safety and quality regulations, (iii) coordinating and evaluating FDA's food surveillance and compliance programs, (iv) coordinating and evaluating cooperating states' food safety activities, and (v) developing and disseminating food safety and regulatory information to consumers and industry. CFSAN's staff numbers 790, according to FDA.[25]

FDA's Center for Veterinary Medicine is responsible for ensuring that all animal drugs, feeds (including pet foods), and veterinary devices are safe for animals, are properly labeled, and produce no human health hazards when used in food-producing animals. The Center employs 247 people at its headquarters, and has a field inspection staff of 91.

The FDA cooperates with about 400 state agencies across the nation that carry out a wide range of food safety regulatory activities. The FDA holds the statutory authority for ensuring the sanitary operation of 560,000 food service establishments; 150,000 retail food stores; 1 million food vending locations; 126,000 Grade A dairy farms; 770 milk pasteurization plants; 750 shellfish processors; 1,100 shellfish shippers; and 850 shellfish-growing areas. However, the state agencies are primarily responsible for their actual inspection. The FDA works with the states to set the safety standards for these establishments and commodities and evaluates the states' performance in upholding such standards as well as any federal standards that may apply.

The FDA also contracts with states to use their food safety agency personnel to carry out certain field inspections in support of FDA's statutory responsibilities. For example, the FDA contracts with states to monitor medicated animal feeds and to investigate incidents of pesticide or drug residues in foods and toxins in shellfish.

(2) The Food Safety and Inspection Service. The FSIS regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat and poultry sold for human consumption. Under the Federal Meat Inspection Act of 1906, as amended, FSIS inspects all cattle, sheep, swine, goats, and equines during slaughtering and processing. Under the poultry Products Inspection Act of 1957, as amended, FSIS is required to inspect "any domesticated bird" being processed for human consumption; however, USDA regulations implementing this law limit the definition of domesticated birds to chickens, turkeys, ducks, geese, and guineas. FSIS also offers a voluntary fee-for-service inspection program for emu, ostriches and rheas (ratites). As mentioned above, the FDA has jurisdiction over the exotic and alternative meats not inspected by FSIS, and shares the responsibility for egg safety with FSIS. The latter is responsible for the safety of liquid, frozen and dried egg products, domestic and imported, and for the safe use or disposition of damaged

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[25] CRS. 98-91 ENR, p. 3. (Reference for all figures in this section.)

and dirty eggs under the Egg Products Inspection Act, as amended. FSIS's current budget is $589 million.[26]

The FSIS inspection force in the field numbers 8,000 and is responsible for inspection at roughly 6,500 meat and poultry slaughtering and processing plants. FSIS personnel inspect all meat and poultry animals at slaughter on a continuous basis and one or more federal inspectors are on line during all hours the plant is operating. Processing inspection does not require a FSIS inspector to remain constantly on the production line or to inspect every item. Instead, inspectors are on site daily to monitor the plant's adherence to the standards for sanitary conditions, ingredient levels, and packaging, and to conduct statistical sampling and testing of products. Because all plants are visited daily, processing inspection also is considered to be continuous.

The FSIS is responsible for certifying that foreign meat and poultry plants are operating under an inspection system that is equivalent to the U.S. system before they can export their product to the United States. FSIS inspectors located in U.S. ports of entry carry out a statistical sampling program to verify the safety of imported meat from cattle, sheep, swine, goats, and equines and imported poultry meat from chickens, turkeys, ducks, geese, and guineas before they are released into domestic commerce. The FDA is responsible for ensuring the safety of imported meat from any other species.

Approximately 27 states operate their own meat and/or poultry inspection programs. The FSIS is statutorily responsible for ensuring that the states' programs are at least equal to the federal program. Plants processing meat and poultry under state inspection can market their products only within the state. If a state chooses to discontinue its own inspection program, or if FSIS determines that it does not meet the agency's equivalency standards, FSIS must assume the responsibility for inspection if the formerly state-inspected plants are to remain in operation. The FSIS also has cooperative agreements with 10 states under which state inspection personnel are authorized to carry out federal inspection in roughly 255 meat and/or poultry plants. Products from these plants may travel in interstate commerce.

(3) National Marine Fisheries Service. Although the FDA is the primary agency responsible for ensuring the safety, wholesomeness and proper labeling of domestic and imported seafood products, the National Marine Fisheries Service (NMFS), within the U.S. Department of Commerce, conducts, on a fee-for-service basis, a voluntary seafood inspection and grading program that focuses on marketing and quality attributes of U.S. fish and shellfish. Agency officials estimate that the program covers about 20 percent of the seafood consumed annually in the United States.[27] If contracted to provide the service, NMFS personnel may inspect fishing vessels and processing plants to ensure that sanitary practices are in keeping with FDA standards; they periodically may

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[26] Ibid, p. 4. (Reference for all figures in this section.)

[27] Ibid, p. 4. (Reference for all figures in this section.)

evaluate products at processing facilities for general condition, wholesomeness and proper grading and labeling; and they may sample products for laboratory testing for chemical and microbiological contamination, decomposition, and species identification. There are roughly 144 NMFS inspectors and about 100 FSIS and state meat inspectors cross-licensed to perform seafood inspection services under this program. In FY 97, $12 million in user fees was collected for inspection services. The agency also spent about $14 million in FY 97 on research in the areas of safety, quality, and identity, to support its inspection program. The primary legislative authority for the NMFS's inspection program is the Agricultural Marketing Act of 1946, as amended.

(4) Environmental Protection Agency. The EPA has the statutory responsibility for ensuring that the chemical used on food crops do not endanger public health. EPA's Office of Pesticide Programs is the part of the agency that (i) registers new pesticides and determines residue levels for regulatory purposes; (ii) performs special reviews of pesticides of concern; (iii) reviews and evaluates all the health data on pesticides; (iv) reviews data on pesticides' effects on the environment and on other species; (v) analyzes the costs and benefits of pesticide use; and (vi) interacts with EPA regional offices, state regulatory counterparts, other federal agencies involved in food safety, the public, and others to keep them informed of EPA regulatory actions. In FY 98, the budget for the food safety activities of the Office of Pesticide Programs is $57.9 million.[28] The Federal Insecticide, Fungicide, and Rodenticide Acts, as amended and the Federal Food, Drug, and Cosmetic Act, as amended are the primary authorities for EPA's activities in this area.

(5) Centers for Disease Control and Prevention. The CDC is responsible for (i) monitoring, identifying, and investigating foodborne disease problems to determine the contributing factors; (ii) working with FDA, FSIS, NMFS, state and local public health departments, universities, and industry to develop control methods; and (iii) evaluating the effect of control methods. In 1995, the CDC launched a collaborative project with the FDA and FSIS -- called FoodNet – to improve the data collection on foodborne illness causes and outbreaks. The FoodNet system includes active surveillance of clinical microbiology laboratories to obtain a more accurate accounting of positive test results for foodborne illness; a physician survey to determine testing and laboratory practices; population surveys to catch illnesses not reported to doctors; and research studies to obtain new and more precise information about which food items or other exposures may cause diseases. FoodNet data will permit the CDC to have a clear picture of the incidence and causes of foodborne illness and to establish baseline data against which to measure success of changes in food safety programs. In FY 97, the CDC had a budget of $4.5 million for its food safety related activities.[29] In support of the Administration's 1997 Food Safety Initiative, Congress appropriated an additional $10 million for CDC's surveillance work in FY 98. The Public Health Service Act, as amended provides the legislative authority for CDC's food safety related activities.

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[28] Ibid, p. 5.

[29] Ibid, p. 5.

(6) The Animal and Plant Health Inspection Service (APHIS). The APHIS is responsible for ensuring the health and care of animals and plants. The APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to animal or plant health. The APHIS identifies research and data needs and coordinates research programs designed to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety. The APHIS indirectly protects the nation's food supply through programs to protect plant and animal resources from domestic and foreign pests and diseases, such as brucellosis and bovine spongiform encephalopathy (BSE, or "mad cow" disease). Of APHIS's $512 million FY 97 budget, roughly $200 million (or 40 percent) was for pest and disease exclusion and $96.5 million (or 19 percent) for pest and disease management (not all of the work in these categories relates directly to food safety, however).[30]

(7) Grain Inspection, Packers and Stockyards Administration (GIPSA). The GIPSA is responsible for sharing information with the FDA concerning food safety and for ensuring the quality of grains for marketing. For example, the GIPSA covers the inspecting of corn, sorghum, and rice for aflatoxin, which causes human illness. The GIPSA carries out its responsibilities under the U.S. Grain Standards Act, as amended, and the Agricultural Marketing Act of 1946, as amended.

(8) Agricultural Marketing Service (AMS). The AMS is primarily responsible for establishing the standards of quality and condition and for grading the quality of dairy, egg, fruit, meat, poultry, seafood, and vegetable products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. The AMS carries out its wide array of programs to facilitate marketing under more than 30 statutes -- for example, the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; and the Export Grape and Plum Act, as amended.

(9) Agricultural Research Service (ARS). The ARS is responsible for conducting a wide range of research relating to USDA's mission including food safety research. The ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended. The ARS performs food safety research in support of FSIS's inspection program. In FY 97, $50 million (or 7 percent) of ARS's research budget was targeted for this purpose.[31]

(10) United States Customs Service. The Customs Service is responsible for collecting revenues and enforcing various customs and related laws. The Customs Service assists both the FDA and FSIS in carrying out their regulatory role in food safety. Examples of Customs' activities

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[30] Ibid, p. 5.

[31] Ibid, p. 5.

include: checking that imported eggs and egg products are accompanied by a foreign inspection certificate; verifying that imported milk and cream shipments are tagged and accompanied by the required FDA permit; checking that imports of pesticides are accompanied by a Notice of Arrival form which is sent to EPA; and sampling imports upon FDA's request.

The Customs Service has a memorandum of understanding with FDA to: i) establish a working relationship between the two agencies for the cooperative enforcement of Section 801 of the Federal Food Drug and Cosmetic Act; ii) establish uniformity in the exercise of the import-sampling and refusal authority; and ii) delegate authority to certain FDA officers to collect samples and issue Notices of Sampling and Notices of Refusal of Admission on behalf of the District Director of Customs.

(11) Federal Trade Commission. The FTC enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC's food safety objective is to prevent consumer deception through the misrepresentation of food.

(12) Bureau of Alcohol, Tobacco and Firearms. The BATF is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.

D. Federal Statutes. There are at least 35 statutes that are associated with regulating food safety. The FFDCA and other statutes have vested the FDA with the responsibility to prohibit entry into interstate commerce of adulterated or misbranded foods and other products. FDA officials are authorized to enter and inspect, at reasonable times, any factory, warehouse, or establishment in which foods are manufactured, processed, packed, or held prior to the introduction into interstate commerce or in a vehicle transporting food. If violations are found, the FDA can request that the Justice Department initiate an injunction, seizure, or prosecution. The FDA also uses a number of administrative enforcement tools. It can send warning letters and other regulatory correspondence, and can detain foods, request voluntary recalls, create import lists, prosecute misdemeanors, and felonies through the Department of Justice. It does not have the power to mandate recalls nor look at all records kept by the plant.

FSIS inspectors, while inspecting each meat and poultry carcass slaughtered and inspecting all meat and poultry processing plants daily, have summary powers to withdraw inspection, condemn foods, stop processing operations, and obtain plant records. FSIS compliance staff investigates any alleged violations of the meat and poultry inspection acts. The FSIS can detain the product in the plant; it can institute a seizure action requesting a federal district court to direct a U.S. Marshall to take custody of the product. It also does not have mandatory recall authority. Both the FDA and FSIS do have the power, if a company refuses to voluntarily recall a product, to issue a press release and a public warning, and may then proceed to detain and seize the products.

The following paragraphs outline some of the statutes that are associated with imported food products.

(1) Federal Food, Drug, and Cosmetics Act.[32] This act authorizes the FDA to regulate food production and manufacturing (except meat, poultry, and egg products, which are covered by separate legislation and are the Agriculture Department's responsibility) to ensure that food is safe, clean, and wholesome and establish reasonable standards of identity, quality, and fill of container for food products. The act also prohibits the interstate commerce of adulterated foods and false or misleading labeling of food products. Under the act, the EPA is responsible for setting tolerances for pesticide residues on food commodities and animal feed marketed in the United States. A food is *adulterated* if it contains substance that may render it injurious to health. A food is *misbranded* if information required by law does not clearly appear on the label.

Section 342 of the Federal Food, Drug, and Cosmetic Act relates directly to food safety and defines the conditions that would deem a food to be considered adulterated and therefore illegal to process and/or sell. Adulteration can be more than just the presence of, or the addition of, something harmful to foods. For example, removing or replacing a valuable ingredient and thus creating a lower-quality product is considered economic adulteration. Adulteration may also occur inadvertently; soil, mold, bacteria, or banned pesticides are all present in the environment and could conceivably become part of a food product without any human involvement. In cases such as these, if an extraneous compound becomes incorporated into a product at a level above a regulatory tolerance level, the product is considered adulterated.

Foods can also become adulterated by being processed, packed, or stored under unsanitary conditions. The FFDCA states that a food is considered to be adulterated ". . . if it bears or contains any poisonous or deleterious substance which may render it [the food] injurious to health." The term "injurious" includes conditions such as the presence of disease-causing microorganisms and natural or man-made toxic substances.

Foods are further considered to be adulterated if "it consists in whole or part of any filthy, putrid or decomposed substances or is otherwise unfit for food." This deals with microorganisms as well as the safety of foods. There is some question as to when a food should be considered unfit for consumption. Some conservative palates would consider snails, squid, or chocolate-covered ants unfit for food. Because most food products may become contaminated by soil or by insects, which may also introduce disease-causing microorganisms, this section of the Act could potentially ban all foods. The law, however, allows the FDA some discretion in defining contamination. Over many years, through the combined efforts of industry scientists working with FDA officials to look at actual food processing lines and current technologies, the FDA has established food defect action levels. These levels are set at points below which there is no hazard to health and at the lowest levels consistent with existing good agricultural and manufacturing practices. Thus, there can be some

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[32] 21 U.S.C. 301.

insect fragments in frozen broccoli or some ground up animal hairs in flour. It is impossible to prevent the occurrence of these contaminants; the defect action level ensures that at the levels of contaminants allowed, the products will be safe if consumed.

The FDA has no authority to enforce on-site inspection of the production of food manufactured aboard. However, in carrying out its obligations for ensuring the safety and quality of food products to the American public, the FDA samples imported products at ports of entry. The U.S. Customs Service has the responsibility of monitoring ports of entry into the United States. The FFDCA gives the Secretary of HHS the right to request a sample of an imported product from the Secretary of Treasury [U.S. Customs Service], when a food shipment arrives at a port. The FFDCA does not require the FDA to sample every imported product.

(2) Federal Insecticide, Fungicide, and Rodenticide Act.[33] This act requires the EPA to register pesticide products, specify the terms and conditions of their use prior to being marketed, and remove unreasonably hazardous pesticides from the marketplace. The act requires the EPA to take into account the economic, social, and environmental costs and benefits in making decisions.

(3) Public Health Service Act.[34] This act provides for federal-state cooperative assistance in preventing the interstate transmission of disease, and thus establishes the FDA's authority for its program for sanitation in milk processing, shellfish, restaurant and retail market operations, and interstate travel conveyances.

(4) Pesticide Monitoring Improvements Act of 1988.[35] This act requires the FDA to: (i) develop new (or modify existing) data management systems to track, summarize, and evaluate pesticide monitoring data; (ii) enter into cooperative agreements with foreign countries to obtain pesticide usage data on crops imported from those countries; and (iii) develop an analytical methods research plan to guide the development of methods to improve the efficiency of food monitoring.

(5) Federal Anti-Tampering Act.[36] This act provides for monetary penalties and imprisonment for tampering with consumer products, including food, and their labeling and packaging that affect interstate and foreign commerce. The act gives the FDA, USDA, and FBI the authority to follow up on tampering violations.

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[33] 7 U.S.C. 136.

[34] 42 U.S.C. 201.

[35] 21 U.S.C. 1401.

[36] 18 U.S.C. 1365.

(6) Agricultural Marketing Act of 1946.[37] This act authorizes the Secretary of Agriculture to provide services upon request to inspect, certify, and identify the class, quality, quantity, and condition of agricultural products shipped or received in interstate commerce. The act also authorizes the Secretary to develop and improve standards of quality, quantity, condition, grade, and packaging and to recommend and demonstrate such standards in order to encourage uniformity and consistency in commercial practices. The Agricultural Marketing Service (AMS), Federal Grain Inspection Service (FGIS), and National Marine Fisheries Services (NMFS) develop standards and perform inspection and grading services under the act. AMS is responsible for dairy products, fruits and vegetables, livestock, meat, poultry, rabbits, and shell eggs. FGIS is responsible for rice, processed grain products, hops, and related commodities. NMFS is responsible for fish and shellfish.

(7) Agricultural Marketing Agreement Act of 1937.[38] This act authorizes the establishment of programs and agreements to regulate the quality, quantity, or container or pack requirements for fruits, vegetables, and certain specialty crops and to regulate the minimum prices paid to producers of milk and dairy products. The act also requires the regulation of certain of these commodities imported into the United States whenever domestic shipments of the commodities are subject to quality regulations under a marketing order.

(8) Federal Meat Inspection Act.[39] This act requires the FSIS to administer an inspection program to ensure that meat and meat products moving in interstate and foreign commerce for use as human food as safe, wholesome, and correctly marked, labeled, and packaged. The act was amended in 1967 to establish the federal-state cooperative program under which the Agriculture Department helps fund state inspection programs conducted by state employees for meat sold in intrastate commerce. It also required state inspection programs to be "at least equal to" the federal program and strengthened the regulation for imported meat.

(9) Poultry Products Inspection Act.[40] This act requires the FSIS to administer an inspection program to ensure that poultry and poultry products moving in interstate and foreign commerce for use as human food are safe, wholesome, and correctly marked, labeled, and packaged. The act was amended in 1968 to establish the federal-state cooperative program under which the Agriculture Department helps fund state inspection programs conducted by state employees for poultry products sold in intrastate commerce. It also required state inspection programs to be "at equal to" the federal program.

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[37] 7 U.S.C. 1621.

[38] 7 U.S.C. 601.

[39] 21 U.S.C. 601.

[40] 21 U.S.C. 451.

E. Food Import System. The FDA and FSIS are the two principal federal agencies responsible for ensuring that the imported shipments of food entering the U.S. are safe. Their systems of inspecting, testing, and approving the release of these food shipments operate independently of each other. To assist these agencies, the U.S. Customs Service provides a number of services, including referring imported shipments for inspection. The Customs Service is the first federal agency that has the opportunity to screen imported food products when they enter the United States. The Customs Service cooperates with FDA and FSIS in carrying out their regulatory roles in food safety.

(1) U.S. Customs Service. Created in 1789, the U.S. Customs Service is one of the federal government's oldest agencies. It is the front-line agency responsible for regulating commerce and detecting contraband at our borders. The Customs Service is responsible for collecting revenue from imports and enforcing various customs and related laws. Customs also processes persons, carriers, cargo, and mail into and out of the United States. In fiscal year 1997, Customs collected about $19 billion in revenues, and processed about 18 million import entries; about 128 million vehicles and trucks; about 706,000 commercial aircraft; about 214,000 vessels; and about 442 million air, land, and sea passengers entering the country.

Customs Service operations are divided into two distinct and separate functional divisions. The "law enforcement" function of the Customs Service is responsible for the enforcement of many federal criminal laws, including Customs statutes (smuggling), drug laws and other criminal offenses that affect the entry of goods, services or persons into the United States. This division is staffed by sworn law enforcement special agents, similar to the agents that staff ATF, Secret Service, FBI and the DEA.

The other division of Customs is responsible for "inspections." This group conducts all inspections at our borders, and they are responsible for policies and procedures related to the entry of goods into the United States. The inspectors who work in this division have no law enforcement powers and must refer any contraband they discover (drugs, tainted food, etc.) to special agents assigned to the Customs Service's law enforcement division for investigation. This distinction is important since the law enforcement group will be presenting evidence at this hearing about their food import cases, but these witnesses have no responsibility for the food import system, which is administered by the inspections side of the Customs Service.

The Customs Service assists both the FDA and FSIS in carrying out their regulatory role in food safety. Examples of Customs' activities include: checking that imported eggs and egg products are accompanied by a foreign inspection certificate; verifying that imported milk and cream shipments are tagged and accompanied by the required FDA permit; checking that imports of pesticides are accompanied by a Notice of Arrival form which is sent to EPA; and sampling imports upon FDA's request.

The Customs Service has a memorandum of understanding with FDA to: i) establish a working relationship between the two agencies for the cooperative enforcement of Section 801 of

the Federal Food Drug and Cosmetic Act; ii) establish uniformity in the exercise of the import-sampling and refusal authority; and ii) delegate authority to certain FDA officers to collect samples and issue Notices of Sampling and Notices of Refusal of Admission on behalf of the District Director of Customs.

(2) FDA Import System. To ensure that FDA is notified of all food products under its jurisdiction that are imported into the United States, an importer must file an import notice along with certain shipping information and, for shipments valued over $1,250, a bond to cover the goods for release with the Customs Service within five days of the shipment's arrival at a U.S. port of entry. The import documents or electronic entry data identify the type of food product, the importer, foreign manufacturer, and country of origin. The bond, which covers potential duties, taxes, and penalties, may allow the importer to retain control of the shipment until FDA decides to inspect samples, test, or release it.[41] If an importer fails to make an import shipment available for FDA's inspection, fails to recondition, or fails to destroy or re-export the shipment, as directed by FDA, Customs may collect penalties against all or part of the bond value.

To assist FDA in reviewing all shipments, the Customs Service's computer system uses the information provided by the importer and FDA-developed screening rates to determine which shipments to automatically release into domestic commerce and which shipments to review further. FDA sets the screening rates using several sources of information, such as the annual work plan, type of product, and past violations of products or shippers. Most shipments that are believed to pose minimal safety risks, such as candy and dried pasta products, are frequently released automatically because they have, historically, low violation rates. FDA releases these shipments a few minutes after the importer enters the information. Other shipments, such as some seafood, are less frequently or never released automatically, because they pose greater potential health risks.

For products not automatically released, Customs forwards shipment information to FDA for further review, through FDA's automated screening system, known as the Operational and Administrative System for Import Support (OASIS). This system was pilot-tested in 1992 and installed at all FDA's district offices by October 1997. Before OASIS was developed, FDA manually tracked shipments through entry documents submitted by importers to the Customs Service. Along with the electronic information provided by the importer, FDA officials use the information in OASIS and other sources as needed -- such as the databases with information on products to be automatically detained and registration numbers for foreign firms -- to determine which samples of imported food shipments should be held for further action, such as inspection and/or laboratory testing, and which can be released without further review. FDA releases most

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[41] Importers generally obtain continuous bonds that provide coverage for multiple shipments over a specified time period. The amount of a continuous bond is based primarily on a percentage of duties paid in the previous year. Importers can also purchase bonds for single shipments (single-entry bonds) in an amount three times the declared value of the shipment. The declared value is based on the cost of the goods to the importer.

shipments not requiring further review within three hours after the importer enters the information. FDA does not visually check or inspect these released shipments.

FDA inspects or conducts laboratory analyses on a small percentage --currently less than two percent annually -- of all types of imported food shipments under its jurisdiction. Inspections may occur at ports of entry, at warehouses or other business establishments. If FDA decides to test an imported food shipment, a FDA inspector collects a sample from the shipment and sends it to a FDA laboratory for analysis. FDA maintains a record of all laboratory test results in its Laboratory Management System database. For samples found to comply with U.S. standards, FDA notifies Customs and the importer that the shipment can be released. For samples found to violate these standards, FDA notifies Customs and the importer that the shipment is refused entry into the United States. Importers generally have three options for handling shipments refused entry. If FDA concurs, importers can (i) recondition the shipment; (ii) destroy it; or (iii) re-export the goods. Whatever option the importer chooses, Customs Service officials are required to supervise proper disposition of the refused shipment.

(3) FSIS Import System. Before foreign firms can export meat and poultry to the United States, FSIS must have determined that the exporting country has a food safety system for these products that is equivalent to the U.S. system. Unlike FDA, FSIS inspectors visually check every imported shipment of foods under their jurisdiction for correct documentation, transportation damage, and correct labeling at FSIS-approved import inspection stations.[42] FSIS conducts more intensive inspections and tests on a portion of the imported shipments -- about 20 percent in 1997 -- to verify the effectiveness of the foreign food safety system. FSIS calls this process "reinspection" because the product has already passed inspection by the exporting countries' equivalent inspection system.

Importers of FSIS-regulated products, like importers of FDA-regulated products, must file an import notice and file a bond with the Customs Service within five days of the date that a shipment arrives at a port of entry to cover their goods for release. Unlike FDA, however, importers must hold shipments at FSIS-registered warehouses for FSIS' inspection until these shipments are released into the domestic market or refused entry. In the case of FSIS-regulated products, unlike FDA regulations, the importer does not retain control over the food shipment pending government inspection.

FSIS inspectors enter the information provided by importers -- such as country of origin, foreign manufacturer, exporting country's health certification, and type of product -- into a centralized computer system. This computer system, which was installed in 1979, is known as the Automated Import Information System (AIIS). The system scans the information it contains to determine if the country, plant, and product are eligible for import into the United States and whether

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[42] FSIS is responsible for processing just 118,000 food entries per year while the FDA has jurisdiction over approximately 2.7 million food entries into the United States.

the shipment will be allowed entry with only a visual check or be subjected to more intensive inspections and tests.

The AIIS system uses computer-assigned screening procedures and individual plants' performance histories to target shipments for more intensive inspection and testing. Under the system, one violation on the previous shipment of a particular product, such as boneless beef, triggers more intensive inspection and testing for the same type product from the same foreign firm until FSIS has found at least 10 successive shipments that are free of violations and meet U.S. standards. Violations that generate more intensive inspections include food products that contain chemical residues or bone fragments, have misidentified products, or have microbial contamination. If the imported products do not meet U.S. requirements, they are stamped "U.S. Refused Entry" and must be exported, destroyed, or converted to animal food. Unlike FSIS, the FDA does not mark adulterated products with "U.S. Refused Entry." According to FDA officials, the FDA does not have explicit statutory authority to place this marking on refused shipments. FSIS uses information on refused shipments to plan inspections in foreign countries.

(4) Customs Brokers. Customs brokers are private individuals or companies, regulated by the U.S. Customs Service, who aid importers and exporters in moving their merchandise through Customs. A customs broker's activities include:

- Preparing and filing entry documentation with the U.S. Customs Service for goods entering the United States;
- Reviewing the classification, duty rate, and assigned value of the imports. If there is a problem or a discrepancy, they pursue the appropriate administrative remedy with the Customs Service;
- Depositing the correct duty payment with the Customs Service on behalf of the importer (though the broker actually pays the duty, the importer is ultimately responsible for payment);
- Securing release of the goods from the Customs Service;
- Obtaining a bonded warehouse if desired by the importer; and
- Arranging delivery of the goods to the importer's warehouse or plant.

Customs brokers charge a fee for these services (usually between $60 and $125 per entry), but no person may conduct these activities unless that person holds a valid customs broker's license which is issued by the Secretary of the Treasury.

To obtain a broker license, an applicant must be a U.S. citizen of good moral character and be at least 21 years of age. The applicant must pass an examination (a score of 75 percent or

higher) that consists of 75 to 100 multiple-choice questions. Once an applicant passes the examination, the Customs Service conducts a background investigation which includes character references, credit references, and arrest records. Each licensed broker is required to submit a report to the Treasury Secretary every three years to show whether the broker is actively engaged in business and, if so, the report must contain the location where business is being conducted.

(5) Importers. An importer can be an individual, group of individual or a business. The U.S. Customs Service does not require an importer to have a license or permit. Depending on the commodity, other agencies may require a permit, license or other certification. All merchandise coming into the United States must clear customs and is subject to a customs duty unless specifically exempted by law from this duty. Clearance involves a number of steps – entry, inspection, appraisal, classification, and liquidation.

To make or file a customs entry, several documents are required: (i) a bill of lading, airway bill, or carriers's certificate as evidence of the consignee's right to make entry; (ii) a commercial invoice, obtained from the seller, which shows the value and description of the merchandise; (iii) entry manifest (Customs Form 7533) or Entry/Immediate Delivery (Customs Form 3461); and (iv) packing lists and other documents, if necessary, to determine whether the merchandise may be admitted. When the entry is filed, the importer indicates the tariff classification and pays any estimated duty and processing fee. A surety bond containing various conditions, including a provision for paying any increased duty that may be later found to be due, may also be required. The importer is authorized to prepare and file entry documents as well as perform any other activities required to gain entry of the product into the United States or the importer may contract with a customs broker to handle these duties.

(6) Bonded Warehouse. Imported food shipments are normally transported from the port to the importer's warehouse or to a bonded warehouse. Duties and processing fees are not paid on shipments placed in bonded warehouses until the goods are released or withdrawn for consumption. Importers may request that the goods be placed in a bonded warehouse in order to repackage, sort, or clean the goods or Customs officials may direct that the goods be delivered to a bonded warehouse in order for Customs officials to conduct an inspection. The importer is responsible for paying any costs associated with unloading and storing the goods; however, bonded warehouses are operated independently of importers.

The Secretary of the Treasury designates facilities as bonded warehouses. These facilities are privately-owned third party secure facilities that are used solely for the storage of imported goods. A customs officer and proprietor have joint custody of all the goods stored in the warehouse. Any required labor associated with the stored goods is performed by the owner or proprietor of the warehouse under supervision of the customs officer. Bonded warehouses give the government more control over the imported goods since an independent third party and not the importer has physical control over the shipments until they are inspected and released by the Customs Service.

F. Investigating and Tracking Foodborne Illness

(1) Key Players and Responsibilities. Four federal agencies are charged with responding to outbreaks of foodborne illness: FDA, CDC, USDA, and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility for public health emergencies and work with the federal government in response to such outbreaks.[43] When an outbreak occurs, particularly one that occurs among several states, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak.[44] The CDC serves as a scientific and analytical resource to these state regulatory agencies. The federal regulatory agencies, including FDA, USDA, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes that have the potential to contaminate the air, land, or waters used to produce the food product.[45] The type of food affected determines which regulatory agency has primary jurisdiction: USDA regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments play a central role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents.[46] Although foodborne outbreaks are sometimes local, most outbreaks implicate federal agency jurisdiction.[47] Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners.[48] Federal involvement is also necessary when

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[43] Food Safety From Farm to Table: A National Food-Safety Initiative. Report to the President. May 1997.

[44] Ibid.

[45] Ibid.

[46] Food Safety From Farm to Table: A National Food-Safety Initiative. Report to the President. May 1997.

[47] Ibid.

[48] Ibid.

contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products.[49] In some instances, on-site assistance is requested by the local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem.[50] For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

(2) The Investigative Process. Foodborne illnesses are investigated for two main reasons. The first is to identify and control an ongoing source by emergency action; product recall, restaurant closure, or other temporary but definitive solutions. The second reason is to learn how to prevent future similar outbreaks from occurring. In the long run this second purpose will have an even greater impact on public health than simply identifying and halting the outbreaks. Because all the answers are not available and existing regulations may not be sufficient to prevent outbreaks, the scientific investigation often requires a careful evaluation of the chain of production. This traceback is an integral part of the outbreak investigation. It is not a search for regulatory violations, but rather an effort to determine where and how contamination occurred. Often, the contamination scenario reveals that a critical point has been lost. Therefore, epidemiologists must participate in traceback investigations.[51]

Because of the short shelf-life and broad distribution of many of the new foods responsible for infection, by the time the outbreak is recognized and investigated the relevant food may no longer be available for culture. Because the contamination may be restricted to a single production lot, blind sampling of similar foods that does not include the implicated lot can give a false sense of security. Good epidemiologic information pointing to contamination of a specific food or production lot should guide the microbiologic sampling and the interpretation of the results. Available methods may be insufficient to detect low-level contamination, even of well-established pathogens.[52]

Public health officials rely on epidemiology to find the source of outbreaks of foodborne illness. Many times, when people are diagnosed with a foodborne illness, their doctor or the

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[49] Ibid.

[50] Ibid.

[51] Emerging Infectious Diseases. Emerging Foodborne Diseases: An Evolving Public Health Challenge. Robert V. Tauxe. Volume 3, Number 4. October-December 1997. P. 9.

[52] Ibid.

laboratory that detects a pathogenic organism in a fecal sample reports the incident to the local county health department. That department, in turn, reports cases periodically to the state department of health. States collect those local data and send reports to the CDC, which updates a national surveillance database.

Until recently, officials at the CDC felt that the data from states did not contain enough detail to present an accurate picture of the scope or causes of foodborne illness. Consequently, in July 1995, the CDC, USDA, and FDA began a cooperative active surveillance project for foodborne disease in targeted locations in the United States. That project initially was called the Sentinel Site Study, and more recently is known as FoodNet.[53]

The purpose of FoodNet is to establish baseline data on the incidence rate of foodborne illnesses caused by seven foodborne bacterial pathogens: *E. coli 0157:H7*, *Campylobacter*, *Listeria monocytogenes*, *Vibrio vulnificus*, *Yersinia*, *Shigella*, and *Salmonella*.[54] The project has three parts:

- Part 1, a laboratory-based surveillance, collects data weekly from medical laboratories to record the number of intestinal bacterial pathogens isolated from stool cultures and to confirm cases of each illness-causing pathogen in a given population;

- Part 2, population-based surveys, collects data to determine the incidence of diarrhea symptoms, and the proportion of people seeking medical attention from doctors;

- Part 3, uses the cases identified in part 1 to further determine what has happened.[55]

Where possible, the project determines what percentage of illness is due to specific foods. The final data on rates of illness will serve to tell policy makers which pathogens cause human illness. Those data will also establish baseline levels of illness with which future studies can be compared to see if food safety regulatory activities lower the incidence of illness.

G. Congressional and GAO Oversight. During the past two decades, the Congress has issued reports and held numerous hearings at which the GAO has released reports and/or provided testimony on the issue of the nation's food safety system.

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[53] Ibid. P.7.

[54] CRS Issue Brief. Food Safety Issues in the 105th Congress. March 30, 1998. P.7

[55] Ibid. P.8.

(1) Senate Report. In December 1977, the Senate Committee on Governmental Affairs issued a six-volume report that addressed various aspects of the federal regulatory process. Volume V included findings on the nature of food safety regulation. The Committee concluded, in part, that:

> "Divided responsibility between the Department of Agriculture and the Food and Drug Administration for food regulation has created a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex."
>
> "Some processing plants are subject to inspection by both USDA and FDA. Where a single food establishment makes both meat and non-meat food products each agency exerts some jurisdiction over a part of the operation -- sometimes with ridiculous results. If a manufacturer produces both vegetable soup and vegetable beef soup (the latter containing more than 2 percent meat), the vegetable beef soup may be processed only in the presence of a USDA inspector. No inspector need be present for production of the vegetable soup. The meat-less vegetable soup, and the conditions under which it is produced will in all likelihood be inspected by FDA only once every few years although the potential hazards associated with the two kinds of soup are essentially the same. A similar situation exists when a food processor makes both shrimp chow mein -- an FDA concern -- and pork chow mein -- a product under USDA's domain."

(2) GAO Reports. The following paragraphs highlight some of GAO's report that were associated with food safety.

(a) In July 1977 (almost 21 years ago), GAO issued a report titled "Food and Drug Administration's Program For Regulating Imported Products Needs Improving." The findings and conclusions in this report applied to imported foods as well as imported drugs, medical devices, and cosmetics. GAO concluded that the:

> "Lack of information on products entering the United States limits the effectiveness of the Food and Drug Administration's efforts to regulate imported products before they are sold to the American public. Without such data the agency cannot determine how effective its import surveillance is; it cannot assess the extent that imports may be violating laws or regulations; and it has no assurance that all imported products are inspected periodically. Given FDA's limited coverage of imported products at the various U.S. ports of entry, additional surveillance measures are needed, particularly against those imported products which continually violate its regulations."

(b) In April 1989, GAO issued a report titled "Imported Foods: Opportunities to Improve FDA's Inspection Program. In this report, GAO presented information on how FDA staff

responsible for inspecting imported products spent their time and identified areas where the efficiency of inspection activities could be improved. GAO concluded that:

> "Because of the increasing volume of imported products entering the country and FDA's concern that only a small portion of them are inspected, FDA needs to improve the efficiency of its inspection operations. In this regard, implementing an automated paperwork review system and using centralized inspection locations have potential for contributing to more efficient operations by reducing the amount of time spent on paperwork and travel. Consequently, FDA inspection staff should be able to devote more of their time to inspecting imported food products."

(c) In August 1991, GAO issued a report titled "International Food Safety: Comparison of U.S. and Codex Pesticide Standards." GAO initiated this review because the Senate Committee on Agriculture, Nutrition, and Forestry was concerned about the possible impacts that harmonization of international food safety standards could have on the safety of foods Americans consume and on the ability of U.S. farmers to export commodities overseas. The Committee asked GAO to undertake a study that would compare current U.S. and Codex food safety standards and the processes used for establishing such standards. GAO concluded that:

> "Many differences exist between U.S. and Codex pesticide standards. These differences are a reflection of both technical factors pertaining to pesticide uses and agricultural practices and factors related to the procedures used to evaluate and establish standards. As long as such differences persist, the potential for international trade problems will remain. Yet reducing potential trade problems by harmonizing general standards could affect food safety."
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> "A greater degree of harmonization may be possible for pesticide standards in particular, but in order to determine if and where such improvements can occur, the United States needs to systematically review and assess existing pesticide-by-commodity standards on a case-by-case basis. Small differences could be adjusted as long as it is clear that unreasonable health risks would not result. Conversely, larger differences may involve consideration of more systemic changes in the way pesticide tolerances have been set, including: risk assessment approaches for carcinogenic pesticides, appropriate definitions for pesticides and commodities, consideration of issues pertaining to good agricultural practices, and methods for recognizing international standards in cases where national standards do not exist."

(d) In June 1992, GAO issued a report titled "Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply." GAO's review focused on whether (i) food inspection systems were logical and consistent, (ii) agencies were efficiently using federal

resources for inspection, and (iii) agencies were effectively coordinating their food safety and quality inspection efforts.

GAO found that inconsistencies and illogical differences between the agencies' approaches and enforcement authorities undercut the system's effectiveness. How frequently a food processing plant is inspected and what actions are taken to enforce food safety standards are determined not by a unified, comprehensive assessment of the risk that specific food products pose to public health but by the legislation that governs the responsible agency. For example, firms that process meat and poultry (under FSIS' regulations are inspected daily, while firms that process seafood, which may be of similar risk, are inspected about once every 3 to 5 years (under FDA's rules). In situations not specifically addressed by law, agencies often determine who has jurisdiction to inspect food by administrative distinctions. For example, agencies have determined who has jurisdiction over inspecting a meat sandwich made with one slice of bread as opposed to a meat sandwich made with two slices of bread.

GAO concluded that federal agencies responsible for food safety and quality inspections could use their resources more efficiently by basing inspection frequencies on risk -- the potential hazards associated with the product, process, and processors' compliance with federal regulations -- and by eliminating duplicative inspections.

(e) In September 1994, GAO issued a report titled "Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food." GAO concluded that:

> "Ensuring the safety of the food supply becomes a greater challenge each year as the number of chemicals in use continues to expand and as additional environmental contaminants become concerns. While federal agencies have improved their assessment and oversight of risk, these efforts have not , or cannot, overcome five basic structural weaknesses in the food safety system:
>
> - A fragmented federal effort to identify chemicals that pose a risk to human health; which results in inconsistent assessments of chemical risks.
>
> - A legal and regulatory infrastructure that permits the use of unapproved chemicals in food.
>
> - A resource-intensive and inefficient compliance monitoring system that by itself cannot detect all chemicals of concern.
>
> - An enforcement system that does not adequately deter or penalize violators.

- An import inspection system that cannot ensure that foods with unapproved or banned compounds are not entering the United States."

Regarding the import inspection system, GAO found that U.S. agencies have no jurisdiction over food producers in exporting countries. As a result, to ensure compliance with U.S. food safety standard, federal agencies must rely on the adequacy of exporting countries' food safety systems and/or U.S. inspection and testing of imported products at the port of entry. However, federal agencies have limited assurance that exporting nations adequately inspect food shipped to the United States, and FDA's inspection resources cannot keep pace with the growing volume of imported food. Moreover, federal agencies may not test some imported products for compounds that are used in exporting countries but are not approved for use in the United States. This occurs because (i) the agencies may have incomplete data on these chemicals and/or (ii) some U.S. inspection programs focus only on domestic compounds of concern. Finally, as a result of weaknesses in its regulatory authorities, FDA has been unable to prevent the distribution of contaminated products to U.S. consumers.

(f) In September 1995, GAO issued a report titled "FDA Import Automation: Serious Management and Systems Development Problems Persist." In 1987, FDA began developing a support and information system to automate and improve its import entry clearance process, which required extensive manual examination of paperwork. Through an automated interface with the U.S. Customs Service, FDA has implemented a portion of this system, now known as the Operational and Administrative System for Import Support (OASIS), to enhance its ability to regulate imported products and to relieve importers and FDA personnel of some of the paperwork burdens associated with processing imported products. GAO conducted this review to assess the progress of and identify any problems associated with FDA's implementation of OASIS, as well as systems development areas needing improvements.

GAO found that although some operational improvements have been made to import operations, FDA has not completed a fully functional system after 8 years and an estimated $13.8 million in system development costs (hardware and software acquisition, telecommunications, and other systems costs). This is due primarily to inadequate top management oversight and an OASIS management team that lacked expertise and skills in systems development.

A July 1994 self-assessment review of this systems effort performed jointly by HHS, Public Health Service, and FDA, found that this project was a high risk for failure and recommended suspending development until a comprehensive review of the system was completed. GAO found that although FDA has begun to address some of the problems identified in the self-assessment, others have not been corrected. In addition, performance measures have not been established and project costs have not been properly accounted for. In its approach to developing OASIS, FDA did not follow generally accepted systems development practices for validating software; conducting user acceptance testing; developing a security plan to safeguard its computer facilities, equipment, and data; and conducting a cost-benefit analysis. GAO concluded that the resulting deficiencies introduce potential risks that OASIS, which is partially implemented, may not perform as needed

and that unsafe products could enter the country. FDA initially halted deployment of all but the initial portion of OASIS until the completion of a system design review. The review, completed in June 1995, concluded that OASIS was not ready for national implementation and recommended an immediate reengineering effort.

Despite numerous hearings and reports stating the need for revisions to the existing food safety system, little has changed in the last twenty years.

H. Report by the National Academy of Sciences (NAS). A series of outbreaks of foodborne disease in the summer and fall of 1997 motivated the Congress to support a study of the need for reorganization of the federal food safety system. The FY 98 USDA appropriation bill (P.L. 105-86) provided $420,000 for a study by the National Academy of Sciences on the scientific and organizational needs for an effective food safety system. The purpose of the study was to assess the scientific and organizational needs for an effective food safety system, including the functions overseen by FSIS, FDA, and other federal, state and local agencies with responsibilities for food safety.[56]

On August 20, 1998, NAS issued its report to Congress. The report, entitled "Ensuring Safe Food: From Production to Consumption," drew three primary conclusions: i) an effective and efficient food safety system must be based in science; ii) to achieve a food safety system based on science, current statutes governing food safety regulation and management must be revised, and iii) to implement a science-based system, reorganization of federal food safety efforts is required.

The report addressed each conclusion and make the following recommendations. First, base the food safety system on science. Second, Congress should change federal statutes so that inspection, enforcement and research efforts can be based on scientifically supportable assessments of risks to public health. In addition, Congress and the administration should require development of a comprehensive national food safety plan. Funds appropriated for food safety programs (including research and education programs) should be allocated in accordance with science-based assessments of risk and potential benefit. Third, reorganization of federal food safety efforts should begin with Congress, which should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education. In addition, Congress should provide the agency responsible for food safety at the federal level with the tools necessary to integrate and unify the efforts of authorities at the state and local levels to enhance food safety.

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[56] 105th Congress, House of Representatives, Conference Report, Making Appropriations for Agriculture culture, Rural Development, Food and Drug Administration, and Related Agencies Programs for the Fiscal Year Ending September 30, 1998, and for Other Purposes.

I. Administration Initiatives. In 1993, as part of the National Performance Review (NPR), Vice President Gore established a NPR Food Safety Working Group. The working group was comprised of 10 members which included representatives of the Agriculture Department, FDA, EPA, and a university professor. This working group's task was to define the parameters of a uniform, scientific, risk-based inspection system to ensure a safe food supply. The working group's report contained six findings:

- The present food protection programs do not adequately meet the current regulatory needs of the country;
- The present food production system is not adequate to fully protect the consumer against foodborne illness;
- The current food protection programs are inconsistent in the intensity and frequency of inspection for foods posing similar risks;
- The present food protection network has inconsistent enforcement authority;
- Food safety research is driven by varying missions from the many agencies for which such research is funded; and
- The current protection system results in overlapping and duplicate inspections.

The working group recommended creating a single food safety agency responsible for administering a uniform set of scientifically based food safety laws.

On January 25, 1997, President Clinton announced a Food Safety Initiative. This initiative focused on improved methods to track and prevent microbial foodborne illnesses. Previous policy emphasized detection and mitigation of chemical contaminants such as pesticide and drug residues. The President called upon all the major food safety agencies to work cooperatively to develop a strategic food safety plan to ensure a safe U.S. food supply. He also asked Congress for a $43.2 million FY 98 appropriation to ensure that the agencies would have the resources to address food safety problems identified by the plan. Released in May 1997 and entitled "Food Safety From Farm to Table," the strategic plan covers five major areas of activity: an early warning system for foodborne disease surveillance; coordination of response to interstate outbreaks; risk assessment and research; improved inspections and compliance; and education on proper food handling.

On October 2, 1997, President Clinton announced another food safety initiative ("Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables") to upgrade domestic and imported food safety standards for fresh produce. This initiative is to ensure that imported fruits and vegetables are as safe as those produced in the United States. The President also asked HHS and USDA to issue guidance in one year on good agricultural and manufacturing practices for growing, processing, shipping, and selling fruits and vegetables. That guidance will consider potential sources

of contamination, such as water, worker sanitation, manure and sludge as fertilizer, and transportation problems, and it will provide a system for trace-back of the products to the growers. It will also consider differences in both crops and regions, and will address food safety concerns throughout the food production and distribution system.

The goal is to improve the sanitation and safety practices of all those seeking to sell domestic or imported produce. Administration officials have stated that the guidance document will not be considered a new regulation or have the force of law; rather it will be considered the best advice of FDA, USDA, and the other federal agencies involved (CDC, EPA, and Labor) on good management practices to guide farmers on how to minimize microbial food safety hazards in the production system.

The guidance reflects the standards for safety agreed to in the World Trade Organization's framework agreement, "Agreement of Sanitary and Phytosanitary Measures." That agreement allows each country to institute a level of protection that is based on science and risk assessment. It allows a country to protect its consumers with stringent safety measures as long as domestic and imported products are treated similarly, and it discourages their use as barriers to trade. All signatories of the agreement (124 countries) have also agreed to base sanitary and phytosanitary measures on international guidelines and obligations that were set under the auspices of international organizations such as the Codex Alimentarius Commission (Codex).[57] When completed this year, the final U.S. guidance to producers and processors of fresh fruits and vegetables will be considered when U.S. officials look at the produce production systems of trading partners.

On August 25, 1998, President Clinton issued an Executive Order establishing the President's Council on Food Safety. The Council will have three primary functions: (i) develop a comprehensive strategic plan for federal food safety activities, (ii) ensure that federal agencies annually develop coordinated food safety budgets, and (iii) oversee federal food safety research efforts. The Secretary of Agriculture, Secretary of Health and Human Services and the Assistant to the President for Science and Technology will serve as Joint Chairs of the Council. The remaining members of the Council will be the Secretary of Commerce, Director of the Office of Management and Budget, Administrator of the Environmental Protection Agency, Assistant to the President for Domestic Policy, and Director of the National Partnership for Reinventing Government.

Other food safety initiatives put forth by the Clinton Administration have focused on domestic improvements, including implementation of seafood HACCP, meat and poultry. In addition, in 1996, President signed two bills into law: the Food Quality Protection Act and reauthorization of the Safe Drinking Water Act.

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[57] CRS. 1998. Food Safety Issues in the 105th Congress. IB 98009, p. 10.

J. Legislation. Federal legislation regulating food safety and labeling has evolved piecemeal over many decades to address particular risks to public health. During the 105th Congress, several bills have been introduced to date:

(1) H.R. 2801, Safe Food Act of 1997. Representative Fazio introduced H.R. 2801 on November 4, 1997, and it was referred to the Committees on Agriculture and Commerce. This legislation would consolidate into a single independent agency in the executive branch the responsibilities regarding food safety, labeling, and inspection currently divided among several federal agencies. Similar proposals were introduced in previous Congresses to deal with what some policy makers deemed a fragmented federal food safety authority. This legislation would combine the activities of several federal agencies performing food safety functions into a single, independent food safety agency.

(2) S. 1465, Safe Food Act of 1997. Senator Durbin introduced S. 1465 on November 8, 1997, and it was referred to the Committee on Governmental Affairs. This legislation contains identical provisions as H.R. 2801.

(3) H.R. 3052. Representative Eschoo introduced H.R. 3052 on November 13, 1997, and it was referred to the Committee on Commerce. This legislation would amend the Federal Food, Drug, and Cosmetic Act to allow the Secretary to deny import of foods produced at a location to which U.S. inspection was denied. The bill also directs the Secretary to develop a plan for the initial implementation of the authority.

(4) S. 1707. Senator Mikulski introduced S. 1707 on March 4, 1998, and it was referred to the Committee on Labor and Human Resources. This legislation contains identical provisions as H.R. 3052.

(5) H.R. 3070, Food Safety Enforcement Enhancement Act of 1997. Representative Pallone introduced H.R. 3070 on November 13, 1997, and it was referred to the Committee on Commerce. This legislation would amend the Federal Food, Drug, and Cosmetic Act to provide for notification and recall of contaminated foods that are under the jurisdiction of the FDA. It also provides for civil penalty assessment and for protection of whistleblowers. Representative Rothman introduced a similar bill (H.R. 4497, Food Safety Enforcement Enhancement Act of 1998) on July 8, 1998, and it was referred to the House Committee on Agriculture.

(6) S. 1264, Food Safety Enforcement Enhancement Act of 1997. Senator Harkin introduced S. 1264 on October 7, 1997, and it was referred to the Committee on Agriculture, Nutrition, and Forestry. This legislation would amend the Federal Meat Inspection Act and the Poultry Products Inspection Act to provide for notification and recall of contaminated meat and poultry and for civil penalty assessment.

(7) S. 1597. Senator Levin introduced S. 1597 on February 3, 1998, and it was referred to the Committee on Agriculture, Nutrition, and Forestry. This legislation would require the

Agriculture Department to establish a food safety rapid response team for emergencies. It would also establish the "National Food Safety Research, Education, and Extension Program" to support research to survey and collect data regarding pathogens.

(8) H.R. 3148. Representative Stabenow introduced H.R. 3148 on February 3, 1998, and it was referred to the Committee on Agriculture. This legislation is identical to S. 1597.

(9) H.R. 1232, Imported Produce Labeling Act of 1997. Representative Bono introduced H.R. 1232 on April 8, 1997, and it was referred to the Committee on Agriculture. This legislation would require retailers to inform consumers of the country of origin of all imported produce, including loose items. Retailers could do so "by means of a label, stamp, mark, placard, or other clear and visible sign on the imported perishable agricultural commodity itself or on the package, display, holding unit, or bin containing the commodity at the final point of sale to consumers. Retailers failing to comply would be subject to monetary penalties.

(10) S. 1042, Imported Produce Labeling Act of 1997. Senator Craig introduced S. 1042 on July 21, 1997, and it was referred to the Senate Agriculture, Nutrition, and Forestry Committee. This legislation is identical to H.R. 1232.

(11) H.R. 1371, Imported Meat Labeling Act of 1997. Representative Chenoweth introduced H.R. 1371 on April 17, 1997, and it was referred to the Committee on Agriculture. This legislation would require meat products -- both imported and those prepared in the United States using foreign meat -- to be labeled to identify the country where the animal was raised before slaughter. Products (including retail products) that lack such information would be considered "misbranded" under the Meat Inspection Act.

(12) S. 617, Imported Meat Labeling Act of 1997. Senator Johnson introduced S. 617 on April 17, 1997, and it was referred to the Committee on Agriculture, Nutrition, and Forestry. This legislation is similar to H.R. 1371, except that it also imposes the same import labeling requirements on meat products from live animals already in the United States, if they have been here for less than 10 days at the time of slaughter.

(13) H.R. 2332. Representative Everett introduced H.R. 2332, a bill to amend the 1930 Tariff Act, on July 31, 1997, and it was referred to the House Ways and Means Committee. This legislation would require that frozen produce be marked with the country of origin on the front panel of the package.

(14) H.R. 4266, Food Safety Enforcement Enhancement Act. Representative Baldacci introduced H.R. 4266 on July 17, 1998, and it was referred to the House Committee on Agriculture. The bill requires any person who has reason to believe meat or poultry is adulterated or misbranded to notify the Secretary of Agriculture. The bill also provides the Secretary with authority for voluntary and mandatory recall authority, and greater authority including civil penalty authority.

(15) H.R. 4080, Importer Food Safety Act of 1998. Representative Dingell introduced H.R. 4080 on June 18, 1998, and it was referred to the House Committee on Commerce. The bill would provide for equivalency authority and country of origin labeling. H.R. 4080 also provides for inspection user fees, and directs the development of faster tests to detect pathogens.

III. PSI CASE STUDY OF TAINTED IMPORTED FRUIT

As part of the Subcommittee's investigation into the safety of imported food, PSI investigators conducted a case study of the food import system -- "from the farm to the table" -- and examined how a microscopic organism made thousands of Americans sick in 1996 and 1997 from eating tainted fruit. PSI's case study focused on an outbreak of *Cyclospora* infection associated with fresh raspberries imported from Guatemala.[58] Multistate outbreaks occurred in 1996 and 1997.

Cyclospora is a parasite composed of one cell, too small to be seen without a microscope.[59] The first know human cases of infection with this parasite were reported in medical literature in 1979.[60] Cases have been reported with increased frequency from various countries since the mid-1980's, in part because of the availability of better techniques for detecting the parasite in stool specimens.[61] Until 1996, most of the documented cases of cyclosporiasis in North America were in overseas travelers.[62] However, two significant outbreaks associated with imported fruit occurred in the United States, one in 1996 and another in 1997.

In 1996, a large outbreak of cyclosporiasis occurred in the United States and Canada. There were at least 1,465 cases of cyclosporiasis reported by 20 states, the District of Columbia, and 2 Canadian provinces.[63] The Centers for Disease Control and Prevention's (CDC) investigation of these cases revealed that the 1996 outbreak was associated with the consumption of Guatemalan raspberries.[64] Of the 1,465 reported cases, 315 were associated with seven states whose Senators are

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[58] In this document, the terms *Cyclospora* and cyclosporiasis are used. For clarification, *Cyclospora* is the parasite or pathogen and cyclosporiasis is the illness caused by *Cyclospora*.

[59] CDC Fact Sheet. *Cyclospora* Infection. October 29, 1997.

[60] Ibid.

[61] CDC Fact Sheet. Cyclospora Infection. October 29, 1997.

[62] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P. 1.

[63] Ibid.

[64] Ibid.

Members of this Subcommittee -- Maine (2), Pennsylvania (29), Connecticut (38), Georgia (5), Illinois (60), New Jersey (103), and Ohio (78).[65]

After this 1996 outbreak the Food and Drug Administration (FDA) and the CDC worked with the Guatemalan Berry Commission to improve the practices for growing and handling raspberries in Guatemala. The Commission voluntarily improved water quality and sanitary conditions and established a farm classification system (with only farms in the best class permitted to export) in an attempt to minimize the possibility that *Cyclospora*-contaminated raspberries would be exported to the United States.[66] Because cyclosporiasis may be a seasonal disease, Guatemalan raspberries were imported without restriction in the fall of 1996, and no cases of cyclosporiasis attributed to eating Guatemalan raspberries were reported to CDC during this time period.[67]

Despite the measures taken by the Berry Commission, another outbreak linked to fresh raspberries occurred in the United States and Canada in April and May 1997.[68] A total of 1,012 cases of cyclosporiasis were reported in 17 states, the District of Columbia and two Canadian provinces.[69] The evidence again was compelling that Guatemala was the major source of the implicated raspberries.[70]

On May 30, 1997, the Guatemalan Berry Commission announced its decision to voluntarily suspend exports of fresh raspberries to the United States.[71] After shipments were suspended, no further outbreaks of cyclosporiasis linked to raspberries were noted in the United States and Canada during the spring and summer of 1997.[72]

On November 20, 1997, Dr. Fred Shank of FDA's Center for Food Safety and Applied Nutrition notified Roberto Castaneda, President of the Guatemalan Berry Commission, that the FDA would not allow fresh Guatemalan raspberries entry into the United States during the period of

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[65] Ibid.

[66] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[67] Ibid.

[68] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[69] Synopsis: 1997 Raspberry-Associated Outbreak of Cyclosporiasis. June 16, 1998.

[70] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[71] Ibid.

[72] Ibid.

March 15 through August 15, 1998.[73] Dr. Shank also informed Mr. Castaneda that this position might change if the source of *Cyclospora* contamination was determined and corrected or if intervention technologies were developed which would prevent cyclosporiasis in humans.[74]

On March 24, 1998, the Vice-Minister of Agriculture, Minister of Health, and President of the Guatemalan Berry Commission submitted a proposal entitled "Model Plan of Excellence for the Export of Raspberries" to the FDA.[75] The proposal requested that seven Guatemala farms be allowed to ship fresh raspberries to the U.S. during the period March 15 through August 15, 1998.[76] On May 19, 1998, however, the FDA notified Guatemala officials that the FDA would consider allowing shipment of fresh raspberries from only two farms when compliance with all aspects of the Model Plan for Excellence had been demonstrated and when certain conditions set out by FDA had been met.[77]

On June 5, 1998, the Vice-Minister of Agriculture notified Joseph Levitt of FDA's Center for Food Safety and Applied Nutrition that the owners of the two farms expressed their willingness to implement the improvements required in order to export raspberries throughout the year and were ready to be visited by the FDA.[78] The Vice-Minister also requested that a third farm be considered by the FDA to export fresh raspberries.[79]

On June 12, 1998, Mr. Levitt informed the Vice-Minister of Agriculture that if the third farm requesting approval to export fresh raspberries complied with the Model Plan for Excellence and met the specific conditions outlined in the FDA's May 19th letter, the farm would be allowed to export

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[73] Letter from Dr. Fred R. Shank to Roberto Castaneda, dated November 20, 1997.

[74] Ibid.

[75] Letter from Guatemala government officials to Janice Oliver, Deputy Director of FDA's Center for Food Safety and Applied Nutrition, dated March 24, 1998.

[76] Letter from Guatemala government officials to Janice Oliver, Deputy Director of FDA's Center for Food Safety and Applied Nutrition, dated March 24, 1998.

[77] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice-Minister of Agriculture, dated May 19, 1998.

[78] Letter from Guatemala's Vice-Minister of Agriculture to Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition, dated June 5, 1998.

[79] Ibid.

fresh raspberries.[80] Mr. Levitt also informed the Vice-Minister that the FDA was making arrangement to visit Guatemala during the week of June 22th.[81]

In mid-June 1998, Toronto health officials reported that 250 people in Canada had become ill with *Cyclospora* from tainted food eaten during May. The health officials identified that raspberries (not from North America) was the common factor in the outbreak.

A. U.S. Financial Assistance to Guatemala. According to press reports and other accounts in the mid-1980's, the U.S. Agency for International Development (USAID) initiated programs in Guatemala to cultivate non-traditional crops for export as alternatives to Guatemala's traditional crops of corn and beans grown for domestic consumption.[82] The implication of the press reports was that the United States has banned the importation of a crop that it paid to establish in a developing country, namely raspberries in Guatemala.

In preparation for this case study, PSI staff sought to independently verify the accuracy of these press reports. The most current results are provided in the following paragraphs. The press reports were confirmed, in part, during an interview of Bruce Brower by PSI staff. Mr. Brower is a group manager of Chemonics International, a company that subcontracted with USAID from 1986-1995 to promote the production of non-traditional agricultural exports (NTAEs) in Central America. USAID employed Chemonics to manage two programs -- PROEXAG and EXITOS - which required Chemonics to provide plants, materials and training to Guatemalan farmers who in turn provided land, labor and pesticides. Mr. Brower told PSI staff that raspberries were among the alternative crops supported through the USAID program. Mr. Brower estimated that USAID provided Chemonics about $7.7 million from 1986 through 1995 for the Central American project and that "well under $1 million" was spent specifically on Guatemalan raspberries. In a subsequent discussion with PSI staff, Mr. Brower indicated that USAID spending on Guatemalan raspberries was more accurately estimated at $100,000.

In response to a PSI written inquiry (dated May 27, 1998) requesting, in part, "the level of U.S. financial assistance (by fiscal year) for the cultivation and development of the Guatemalan raspberry crop during the past 15 years," USAID responded in a June 12th letter that:

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[80] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Guatemala's Vice-Minister of Agriculture, dated June 12, 1998.

[81] Ibid.

[82] "Imports Swamp U.S. Food-Safety Efforts," NEW YORK TIMES, Sep. 29, 1997.

> "Raspberries were among the crops identified but their production costs pushed raspberry production to a producer group at an economic level greater than the target population for USAID programs. These producers worked on their own to develop their product market, i.e., without direct USAID program financial support."

When the author of the USAID letter was questioned about the response, she indicated that it was her understanding that raspberries were first funded in the mid-1980's by USAID through the PROEXAG program. It was also her understanding, however, that the cost of growing raspberries was excessive and prevented the USAID program from reaching the most impoverished Guatemalans. As a result, the raspberry program was terminated in the mid-1980's. When confronted with the conflicting information supplied to the Subcommittee by Chemonics as well as the conflict in USAID's written response to the PSI's inquiry, the USAID official again reiterated that it was her understanding that U.S. funding for raspberry crops had ceased after a brief period in the mid-1980's.

In a subsequent phone call on the same day, the USAID official amended her earlier statements. She stated that USAID provided about $85,000 to support the Guatemalan raspberry crop from 1985 to 1994. She indicated that the money spent on raspberries comprised "less than 1 percent" of the PROEXAG and EXITOS budgets.

Raspberries and blackberries are not native to Guatemala.[83] Blackberries were first introduced and shown to successfully thrive in Guatemala during the late 1980's.[84] After the blackberry success, raspberries were introduced to Guatemala in the early 1990's.[85] The first large crop of Guatemalan raspberries exported to the United States was in 1995, with larger export yields the following two years.[86] In fact, the number of raspberry farms grew from 12 in the early 1990's to about 150 in 1998.[87]

B. Exports of Guatemala Raspberries. Raspberries are grown by individual farmers and then either exported directly to foreign markets or sold to Guatemalan companies for export. Guatemalan fresh raspberry exports have grown tremendously in the last few years. Both the number of producers and land under cultivation have increased. Total raspberry exports increased from

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[83] FDA's Guatemalan Farm Trip Report. March 5-10, 1998. P. 2.

[84] Ibid.

[85] Ibid.

[86] Ibid.

[87] PSI staff interview with Bruce Brower (12 farms) and PSI staff telephone conversation with Roberto Rosenberg of Guatemalan Embassy (150 farms).

184,606 flats in the 1994-95 harvest year to 299,317 flats in the 1995-96 harvest year.[88] One flat of raspberries weighs approximately 5 kilograms.[89] In May 1995, seven Guatemalan exporters reported exporting approximately 55,951 flats of raspberries to the United States; in May 1996, eight Guatemalan exporters exported a total of 75,824 flats.[90]

Although Guatemala exports raspberries to Europe, the U.S. receives 98 percent of Guatemala raspberry exports.[91] The proximity of the U.S. to Central America permits Guatemalan raspberries to enter the U.S. and reach their final destination within hours to several days after harvesting. This quick transit time suits the raspberries' storage requirements as they have a shelf-life of only 7 to 10 days once harvested.[92] Miami is the largest port of entry for U.S. raspberry imports (88 percent) from Guatemala followed by minimal imports to New York, Houston, Washington, D.C., and Los Angeles.[93] Raspberry exports from Guatemala occur year-round, but larger quantities are exported in October, November, May, and June. These quantities coincide with peak harvest seasons, and the low seasons for Chilean and California raspberries.

C. Raspberry Production Process. Berries were first introduced in Guatemala for export about 10 years ago. Over the last 4 to 5 years, Guatemala has become one of the world's leading sources of raspberries and blackberries. The industry has developed primarily in the central highland region of Guatemala. The climatic conditions are quite favorable for certain varieties of raspberries and the rich, volcanic soil facilitates rapid growth and excellent yields. Because of the climate and soil, raspberries can be manipulated through planting and pruning practices to come into harvest on demand given about 7 months lead time. The California season is generally late May through early October. So the export season for fresh Guatemalan raspberries is normally late October through May.[94]

(1) Berry Development. For seedlings to become flowering plants requires approximately six months. Another six weeks is required for the raspberries to be ready for harvest.

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[88] CDC Foreign Trip Report -- Guatemala. December 20, 1996. P.2.

[89] Ibid. P.2.

[90] Ibid. P.2.

[91] Ibid. P.2. The dependence on exports to the United States magnified the economic impact on Guatemala when the United States decided to halt the imports of raspberries after the 1996 and 1997 outbreaks of *Cylospora*.

[92] Ibid. P.2.

[93] Ibid. P.2.

[94] Picha, D.H. 1997. Background Information on Growing and Harvesting Practices. Presented at meeting in Washington DC, 7/23/97.

Raspberry plants are grown--typically, in hedgerows supported by canes and metal wires. The plants may or may not be tied to the wires individually. The fruit is grown 3 to 4 feet off the ground and, therefore, no direct contact occurs between the fruit and the soil. The plants are watered using drip irrigation. A drip irrigation system typically consists of a piece of plastic tubing running along the ground the length of the row. The underside of the tubing has small holes so the ground can be wet slowly over a long period of time. Thus, no direct contact occurs between the fruit and the water.

(2) Harvesting. Raspberries are harvested by hand, primarily by women. Ripe berries can be pulled from the plant very easily with bare hands leaving the cap on the vine. The pickers generally carry plastic trays strapped around their waists to keep their hands free. The plastic trays contain small plastic baskets into which the berries are placed. Once the baskets are full, the tray is taken to a packaging shelter so the berries can be sorted and packed. Raspberries are always picked dry and are NOT washed at any point prior to sale because they are very susceptible to mold.

(3) Sorting and Packing. Sorting is carried out in enclosed structures. Typically, the structures have poured concrete floors and screened pass-through windows. By passing the trays brought from the fields through a window, tracking of dirt from the field into the packing shelter avoided. In addition, some farms use foot baths placed just outside the packing shelter door to clean shoe-bottoms before entering. Berries are generally sorted on large tables with smooth, white surfaces under a covered fluorescent light. Raspberries to be sold fresh are generally packed in half-pint plastic containers called clamshells. Clamshells are packed in cardboard flats.
A flat holds 12 clamshells. Berries which are too ripe to be sold as fresh are typically put in five gallon plastic pails for freezing.

(4) Shipping. For shipping, the cardboard flats are packed in 3' x 3' x 4' E-containers. E-containers are styrofoam-insulated cardboard boxes. Ten flats fill an E-container. Gelpacks are added to keep the berries cold during international shipping. The E-containers are transported in refrigerated trucks from exporter warehouses to the airport. The trucks arrive at the airport between 11 p.m. and midnight. Upon arrival, the berries are held in cold storage at the cargo loading and storage area. Between 2 a.m. and 4 a.m., the berries are loaded onto either a cargo or passenger plane. All fresh raspberries from Guatemala are shipped by air to the U.S.

(5) Border Inspection. Miami, Florida is the principal port of entry for fresh Guatemalan raspberries, with approximately 88 percent of the berries passing through its airport. After arriving in Miami, the berries are unloaded from the planes and must pass through a USDA cargo clearance area. Each cargo clearance area contains an inspection table where produce and flowers are inspected. Here, E-containers are opened and the gelpacks are discarded. USDA inspectors (Animal and Plant Health Inspection Service) remove clamshells from the flats, open them, and dump the contents on the table. After inspection for insects (not food safety), the berries are placed back in their clamshells, replaced in their flats, and returned to their storage locations before being collected by the Miami-based importers.

(6) U.S. Distribution. Some Miami-based importers bring the raspberry flats to a blast cooler for rapid cooling following inspection. After 60 to 90 minutes of cooling at 34 degrees Fahrenheit, the berries are moved to coolers, or large refrigerated storage rooms, maintained between 34 and 38 degrees Fahrenheit where they remain until they are shipped to distributors. Raspberry flats are shipped to other distributors in one of two ways. If they are transported in a non-refrigerated truck they are repackaged into E-containers with several new gelpacks placed between the flats of the top layer. If they are shipped in a refrigerated truck, the flats are stacked on a pallet without gelpacks. Distributors fill and deliver orders for fresh raspberries placed by retail outlets and food service establishments. Upon receipt, fresh produce is stored briefly until displayed for sale or prepared for consumption.

D. *Cyclospora* - the Parasite. *Cyclospora cayetanensis* is a protozoan coccidian parasite. A one-celled organism, it is related to other organisms such as *Toxoplasma* and *Cryptosporidium*. It is a prototypical emerging pathogen. *C. cayetanensis* is unusual in that it is not immediately infectious when excreted. Under optimal conditions, it matures in days to weeks, so direct person-to-person spread is very unlikely. An outbreak following a meal is probably not caused by the food handler. The organism appears to be seasonal, and in most places where it has been studied, it occurs in the spring or summer and causes little or no disease during the fall or winter. Infection has been reported throughout the world, and the key studies have been conducted in Peru and Nepal. Disease caused by *C. cayetanensis* is characterized by watery stools, nausea, weight loss, low-grade fever, fatigue, or any combination of these symptoms. The disease (which is easily treatable) can be quite protracted, and without treatment, relapse can occur. The mean incubation period of one week complicates the epidemiology; cases may not be recognized until two weeks after people have been exposed.[95]

E. Outbreaks of *Cyclospora* Infection

(1) 1996 Outbreaks. In 1996, a total of 1,465 cases of cyclosporiasis (the disease caused by the *Cyclospora* parasite) were reported by 20 states, the District of Columbia, and 2 Canadian provinces. Of these cases, 978 were laboratory confirmed and 725 were associated with 55 events that were held from May 3 through June 14, 1996. Raspberries were definitely served at 50 of the events and may have been served at four other events.[96]

Of the 1,465 cases, 725 were associated with a cluster and 740 were sporadic.[97] A cluster was defined as a group of two or more cases among persons who, during May 1 through August 31,

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[95] Majkowski, J. 1997. Strategies for Rapid Response to Emerging Foodborne Microbial Hazards. Emerging Infectious Diseases. Volume 3, Number 4.

[96] The New England Journal of Medicine. An Outbreak in 1996 of Cycloporiasis Associated with Imported Raspberries. May 29, 1997. P. 1.

[97] Ibid. P. 2.

1996, shared at lease one meal or food item at an event (e.g., a luncheon or conference) and began to have at least one gastrointestinal symptom 12 hours to 14 days later. At least one case per cluster had to be laboratory-confirmed; clinical case definitions for probable cases varied. Persons who attended the events associated with cases of cyclosporiasis were interviewed about symptoms and their consumption of food and beverages at the event.[98]

Sporadic cases were not associated with identified clusters, were laboratory confirmed, were characterized by the development of gastrointestinal symptoms during May 1 through August 31, and occurred in persons who had not traveled outside the United States or Canada during the two weeks before the onset of symptoms.[99]

The CDC (along with officials from the FDA and state health departments) attempted to trace the sources of raspberries for the 54 events at which raspberries were or may have been served. The CDC was able to obtain well-documented data on the source for 29 events. This data showed that the raspberries served at 21 of the events definitely were from Guatemala and those served at 8 events could have originated in Guatemala.[100] Because exporters typically combined raspberries from multiple farms in a shipment, the CDC could identify only a group of contributing farms rather than one source farm.[101]

To identify the sources of implicated raspberries, the CDC obtained dates of purchase and shipment. The CDC used airway bill numbers supplied by importers to identify shipments and exporters and then farms that contributed to shipments. A well-documented tracing of the source was one in which each step from consumers back to farms was confirmed verbally and in writing (e.g., through copies of invoices). The CDC visited farms and exporters in Guatemala to investigate the ways in which raspberries were grown and handled. The CDC also investigated the way in which berries were inspected in the Miami airport.[102]

The CDC concluded that its investigation of a large outbreak of cyclosporiasis implicated Guatemalan raspberries.[103] The CDC could not assess the true magnitude of the outbreak; most cases

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[98] Ibid.

[99] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P.2. [All of the *Cyclospora* cases reported from Maine were classified as sporadic.]

[100] Ibid. P.5.

[101] Ibid. P.6.

[102] Ibid. P.4.

[103] Ibid. P.7.

were probably not diagnosed or unreported. For salmonellosis, which is a more familiar and easily diagnosed condition than cyclosporiasis, the number of cases reported to the CDC probably represents only 1 to 5 percent of all cases of infection in a year.[104] During routine testing for ova and parasites, stool specimens are not usually examined for *Cyclospora*, and many laboratories do not yet have the expertise to identify it. Experienced personnel in a few sites were instrumental in detecting the outbreak of cyclosporiasis at its inception in May 1996, and subsequent media coverage most likely facilitated the identification of cases.[105]

The mode of contamination of the raspberries remains unclear. One hypothesis is that raspberries became contaminated through spraying with insecticides and fungicides that had been mixed with contaminated water. Although the CDC did not determine how water supplies on different farms could have become contaminated during the same period, many water supplies were vulnerable to contamination because, for example, they were suboptimally constructed or maintained wells near deep pit latrines or seepage pits. They may have been particularly vulnerable during the rainy season (e.g., from surface-water runoff), which is when the 1996 outbreak occurred.[106]

(2) 1997 Outbreaks. The CDC is still in the process of finalizing the results of the 1997 outbreak. The CDC, however, provided the Subcommittee with the following preliminary information. Between April 1 and May 26, 1997, a total of 1,012 cases of cyclosporiasis were reported in 17 states, the District of Columbia and two Canadian provinces.[107] These cases were linked to fresh Guatemalan raspberries.[108] The investigation of the outbreak focused on clusters of cases of cyclosporiasis that were associated with various events, such as wedding receptions. Specifically, 762 cases were associated with 41 cluster events and 250 cases were sporadic.[109]

For the 514 cases that were first reported and investigated, the CDC has published the following results. As of June 11, 1997, there were 21 clusters of cases of cyclosporiasis reported from eight states (California, Florida, Maryland, Nebraska, Nevada, New York, Rhode Island, and Texas) and one province in Canada (Ontario).[110] These clusters were associated with events (e.g., receptions, banquets, or time-place--related exposures that occurred during March 19 through May

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[104] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P.7.

[105] Ibid.

[106] Ibid.

[107] Synopsis: 1997 Raspberry-Associated Outbreak of Cyclosporiasis. June 18, 1998.

[108] Ibid.

[109] Ibid.

[110] CDC Morbidity and Mortality Weekly Report. June 13, 1997. P.1.

25, 1997, and comprised approximately 140 laboratory-confirmed and 370 clinically-defined cases of cyclosporiasis.[111] In addition, four laboratory-confirmed sporadic cases were reported in the United States and Canada.

Fresh raspberries were served at 19 of the 21 events and were the only food in common to all 19 events, which occurred in April and May 1997.[112] At 6 of the 19 events, raspberries were the only type of berry served or were served separately from other berries; at 13 events, raspberries were included in mixtures of various types of berries.[113] Eating the food item that included raspberries was significantly associated with risk for illness for 7 of the 15 events for which epidemiologic data was available (including for three of the events at which raspberries were not served with other types of berries) and was associated with illness but not significantly for six events (i.e., all or nearly all ill persons ate the berry item that was served).[114]

Guatemala was identified as one of the possible sources of raspberries for all eight events for which traceback data was available (i.e., Guatemala was the source of at least one of the shipments of raspberries that could have been used) and as the only possible source for at least one of these events and perhaps for two others.[115]

(3) 1998 Canadian Outbreak. On June 11, 1998, Toronto Public Health issued a media release announcing that they were investigating seven outbreaks of *Cyclospora* infection related to food eaten between May 7 and May 15.[116] The release also stated that more than 60 people had become ill with *Cyclospora* after attending various events in the City of Toronto.

On June 19, 1998, Toronto Public Health issued a media update stating that about 250 people had confirmed or suspected *Cyclospora* infection -- 160 of these were associated with 13 events, such as private parties and weddings.[117] The release also stated that the source of the outbreak was still unknown; however, a common item in all the events was imported raspberries. In addition, the media update stated that health officials were interviewing more than 700 people who attended the various events where people became ill.

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[111] Ibid.

[112] Ibid.

[113] Ibid.

[114] Ibid.

[115] Ibid.

[116] Toronto Public Health Media Release. June 11, 1998.

[117] Toronto Public Health Media Update. June 19, 1998.

On June 23, 1998, Toronto Public Health issued a second media update announcing that Dr. Barbara Yaffe, Associate Medical Officer of Health, had briefed the Board of Health on the *Cyclospora* outbreak.[118] Specifically, about 284 people had confirmed or suspected *Cyclospora* infection -- 170 of these were associated with 18 events, such as private parties and weddings.[119] The media update stated that raspberries eaten at several of the events investigated so far were believed to have originated in Guatemala.[120] The media update also stated that Toronto Public Health was working with local health units, Health Canada, the Ontario Ministry of Health, the Canadian Food Inspection Agency, and the CDC in Atlanta to find the source of the outbreak.

The Board of Health has asked the Public Health department to provide a detailed report on the outbreak when the current investigation is complete, along with recommendations for the labeling of fresh produce with the name of the country or place of origin. The Board also has asked the department to consider recommending a ban on the importation of Guatemalan raspberries, as is currently in place in the United States, if they are found to be the source of the current outbreak.

F. Guatemala Initiatives. After the Guatemalan raspberries were implicated in the 1996 and 1997 outbreaks of *Cyclospora*, Guatemala began implementing several initiatives to ensure that Guatemala's agricultural products meet the highest standards of quality.

(1) High Level Commission for Food Safety. Guatemala created a High Level Commission for Food Safety. The Commission is comprised of the Ministries of Agriculture, Health and Economy in coordination with the Non-Traditional Products Exporters Association. The Commission created five working groups -- Research, Epidemiology and Environment; Treatments Evaluation; Inspection, Certification and Verification; Commercial Promotion; and Commercial Practices. Guatemala also implemented a Sanitary and Quality Assurance System Program (S&Q), that includes Hazard Analysis of Critical Control Points (HACCP) standards and FDA's future Good Agricultural Practices/Good Manufacturing Practices (GAP/GMP) voluntary guidance for fruit and vegetables.

(2) Model Plan of Excellence for the Export of Raspberries (MPE). Guatemala also created the MPE which builds on the S&Q program and adds additional stringent standards to the production, processing, handling, and shipping of raspberries.

On March 24, 1998, Guatemala government officials submitted a proposal ("Model Plan of Excellence for the Export of Raspberries") to the FDA which requested that a limited number of Guatemalan farms be allowed to export fresh raspberries to the United States from March 15 through

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[118] Toronto Public Health Media Update, June 23, 1998.

[119] Ibid.

[120] Ibid.

August 15, 1998. The plan was based on the knowledge and experience gained by Guatemala during the last two years regarding food safety procedures.

The objective of the MPE is to assure only safe raspberries are produced in Guatemala and exported to the United States. The MPE includes the implementation of Good Management Practices in farms and exporter plants and monitoring system during the picking, classification, packaging and transportation of the fruit. All these activities will be supervised directly by an inspector of the Integral Program of Agricultural and Environmental Protection (PIPAA).

The first activity in the design of the MPE was the selection of the farms to participate in it among the ones classified as "low risk farms" carried out by PIPAA. For this selection, PIPAA considered the infrastructure conditions, good agriculture and manufacturing practices, records management, and water quality. The framework of the MPE is fourfold -- quality assurance, training on good hygienic practices, control origin of fruit, and trace-through.

Guatemala also developed a regulation of the sanitary control system for production farms and packaging plants of raspberries and blackberries. The objective of the regulation is to regulate the production and commercial activity of raspberries and blackberries to guarantee the wholesomeness of the product. Guatemala also developed a "Guide of Minimum Requirements for Production and Packaging Units of Raspberries and Blackberries". The primary objective of this guide is to establish a baseline for the implementation of a system of Good Manufacturing Practices (GMP) and the use of HACCP in production and packaging units.

On May 19, 1998, the FDA responded to Guatemala's request that a limited number of Guatemalan farms be allowed to begin exporting raspberries to the United States.[121] Specifically, FDA's stated, in part, that:

> "We are aware of the imprecision of the scientific data regarding the source, biology, and virulence of *Cyclospora*. In the absence of such precise information, FDA cannot recommend with certainty measures that will prevent the contamination of fresh raspberries by this parasite. However, current scientific information is consistent with viewing *Cyclospora* as a waterborne fecal-oral contaminant. We, therefore, have reviewed your proposal in light of the operating assumption that *Cyclospora* is a waterborne organism that may be transmitted by water or humans via the fecal-oral route."

While the FDA response acknowledged that the Guatemalan berry industry had made improvements in water quality, sanitation, and employee hygiene at individual farms, the FDA specified that it did

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[121] Letter from Joseph A. Levitt, FDA's Director of Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice Minister of Agriculture, dated May 19, 1998.

not have sufficient information to confirm that adequate interventions had been implemented for all of the farms identified in the proposal. The FDA, however, did agree to consider allowing shipment of fresh raspberries from two of the proposed farms when compliance with all aspects of the MPE had been demonstrated and when other specific conditions specified by the FDA had been met. The specific conditions include:

- Biological filters (0.5 micron size) must be installed for all water used for fumigation, cleaning and sanitation. The filters must be subjected to a testing protocol that would detect leaks or any other factor that would reduce filter efficiency and effectiveness. Any filter that fails the testing or later leaks or loses its effectiveness or efficiency must be immediately replaced.

- Assurance that prior to the installation of filters, water has not been used directly on fresh raspberries destined for export to the U.S.

- Integral Program of Agricultural and Environmental Protection (PIPAA) will reinspect the farms prior to harvesting fresh raspberries for export to the U.S., and will collect water samples after filtration for microbial analysis.

- Adequate supervision of farm workers to assure proper attire and appropriate employee sanitation practices, including adequate hand washing prior to picking, selection, and packing of fresh raspberries. Supervisors must have received proper training and be qualified to carry out their responsibilities.

- Assurance that PIPAA inspectors on farms and in plants have received proper training and are qualified to carry out their responsibilities.

- Assurance of adequate and properly used toilet facilities and supplies, and supervision of traffic into the selection area.

- The implementation of a surveillance program to ensure that workers are not asymptomatic or symptomatic for diarrheal disease as described in the "Protocol for the Epidemiological Surveillance of Risk Factors on Workers of Berry Producing Farms."

- Assurance that the flats of fresh raspberries leaving the farms will not be tampered with and will arrive intact as the exporters' warehouse and at the cargo loading and storage area in Guatemala City.

- A comprehensive monitoring program with checklist providing documentation that each of the farms has instituted all of the control practices listed above, and that there is a schedule of PIPAA inspections to assure that the controls remain in place throughout the growing and shipping season.

The FDA informed Guatemala that after the intervention strategies had been implemented, FDA would visit the two farms. Once all controls and operations are in place, FDA agreed to allow the shipment of fresh raspberries from the two farms to the U.S.

On June 5, 1998, the Vice-Minister of Agriculture notified Joseph Levitt of FDA's Center for Food Safety and Applied Nutrition that the owners of the two farms expressed their willingness to implement the improvements required in order to export raspberries throughout the year and were ready to be visited by the FDA.[122] The Vice-Minister also requested that a third farm be considered by the FDA to export fresh raspberries.[123] On June 12, 1998, Mr. Levitt informed the Vice-Minister of Agriculture that if the third farm requesting approval to export fresh raspberries complied with the Model Plan for Excellence and met the specific conditions outlined in the FDA's May 19th letter, the farm would be allowed to export fresh raspberries.[124] FDA officials visited Guatemala during the week of June 22nd and continue to evaluate whether to allow Guatemala to export raspberries to the United States.

IV. WITNESSES

A. As of this date, the Members of Congress who have asked to testify before the Subcommittee include Senators Coverdell of Georgia, Mikulski of Maryland and Kennedy of Massachusetts.

(1) **Senator Coverdell** has introduced S. 2025, Food Research, Education, Safety, and Health Act of 1998, or the F.R.E.S.H. Act. This legislation would provide $51 million in funding for consumer education, research (including irradiation research), grants and demonstration projects, and new inspectors. Senator Coverdell has been a vocal advocate for imported produce.

(2) **Senator Mikulski** has introduced S. 1707, the Safety of Imported Food Act of 1998. This legislation is the primary vehicle for so-called "equivalency". S. 1707 amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem imported food adulterated if it has not been prepared, packed, and held under conditions meeting FFDCA requirements for domestic food. The bill would allow the Secretary to deny import of foods produced at a location to which U.S. inspection was denied. The bill also directs the Secretary to develop a plan for the initial implementation of the authority. This legislation is strongly supported by the Administration.

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[122] Letter from Guatemala's Vice-Minister of Agriculture to Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition, dated June 5, 1998.

[123] Ibid.

[124] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice-Minister of Agriculture, dated June 12, 1998.

(3) **Senator Kennedy** is a co-sponsor of S. 1707. He supports more spending to employ additional food safety inspectors. Senator Kennedy is also interested in imposing a user fee on the imported food industry.

B. Representatives from the Executive branch agencies (FDA, FSIS and Customs Service) which have federal regulatory authority over imported foods will testify.

(1) **William Schultz** is FDA's Deputy Commissioner for Policy. Mr. Schultz spearheaded FDA's role in the President's tobacco initiative and he previously worked as counsel to both Congressman Henry Waxman and Public Citizen. FDA will use this opportunity to argue that the FDA should be given equivalency authority, a larger budget, and the ability to levy civil penalties. This will be an opportunity to ask very tough questions about the flaws in the current food safety system, regulatory changes that could be made to remedy current problems, failure to implement an effective tracking system for bad actors, and instances of fraud and deception.

(2) **Thomas J. Billy** is the Administrator of the Food Safety and Inspection Service. Before joining the USDA, Mr. Billy worked at FDA where he developed an innovative HACCP program for seafood. Mr. Billy also worked for 17 years within the National Marine Fisheries Service. FSIS testimony regarding changes to the food safety inspection system will likely focus on the success of the meat and poultry inspection equivalency program. Although largely an indictment of FDA import admission procedures, the April1998 GAO report supplied to PSI also faulted FSIS for its use of violation history alone to determine which shipments of imported goods should be targeted for inspection.

(3) **Raymond J. Kelly** was just recently appointed Commissioner of the U.S. Customs Service. Mr. Kelly is a lawyer who has devoted his life to law enforcement. Mr. Kelly served as the Undersecretary for Enforcement of the Treasury Department from 1996 until his August 1998 appointment as Customs Commissioner. Mr. Kelly previously worked for 25 years in the New York City Police Department where he rose through the ranks to become Commissioner in 1992. Based on the Customs Service's testimony at the September 10th hearing, Mr. Kelly is likely ask for statutory changes in their authority to punish import violators.

(4) **Dr. John C. Bailar** was Chair of a committee established by the National Academy of Sciences to (i) assess the effectiveness of the current system to ensure safe food, and (ii) provide recommendations on scientific and organizational changes needed to increase the effectiveness of the food safety system. Over a recent 6-month period, the committee held three meetings as well as two open forums where agency representatives and relevant stakeholders discussed the food safety system. The committee also reviewed many documents, including reports on how other countries are reshaping their systems. Dr. Bailar will be able to discuss the various findings and recommendations contained in the committee's report which was entitled "Ensuring Safe Food: From Production to Consumption."

C. The industry groups which will testify are National Food Processors Association, Grocery Manufacturers of America, Food Marketing Institute, and United Fresh Fruit & Vegetable Association.

(1) **National Food Processors Association** (NFPA) is a scientific and technical trade association for the food processing industry. Its members process and package fruits, vegetables, meat, fish, and specialty food and beverages products using a variety of technologies including canning, freezing, refrigeration, dehydration, and aseptic manufacturing. On behalf of its members, the NFPA addresses scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. Dane Bernard will be testifying for the National Food Processors Association.

(2) **Grocery Manufacturers of America** (GMA) is the world's largest association of food, beverage and consumer brand companies. Its members have combined U.S. sales of more than $430 billion, employing more than 2.5 million workers in all 50 states. GMA applies legal, scientific and political expertise from its member companies to vital food and public policy issues affecting the industry. Led by a board of 44 Chief Executive Officers, GMA speaks for food and consumer brand manufacturers at the state, federal and international levels on legislative and regulatory issues. Dr. Stacey Zawel will be testifying for the Grocery Manufacturers of America.

(3) **Food Marketing Institute** (FMI) is a nonprofit association conducting programs in research, education, industry relations and public affairs on behalf of its 1,500 members including their subsidiaries–food retailers and wholesalers and their customers in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $220 billion–more than half of all grocery store sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms and independent supermarkets. Its international membership includes 200 members from 60 countries. Timothy M. Hammonds will be testifying for the Food Marketing Institute.

(4) **United Fresh Fruit & Vegetable Association** (UFFVA) is a trade association representing the fresh fruit and vegetable industry and has a membership of 1,300 who grow, pack, ship and distribute the majority of produce consumed by Americans. This past year, UFFVA issued a document prepared by a coalition of industry organizations entitled "Industry wide Guidance to Minimize Microbiological Food Safety Risks For Produce" to serve as a tool and an "agreed-upon yardstick" for produce industry operators. Dr. Nancy Nagel will be testifying on behalf of the United Fresh Fruit & Vegetable Association.

D. The consumer groups we will hear from are the American Public Health Association, the Safe Food Coalition, the Public Voice for Food & Health Policy, and the American Council on Science and Health.

(1) **American Public Health Association** (APHA) is comprised of over 30,000 individual members and 20,000 additional state and local affiliate members and represents more than

75 disciplines in public health and related fields. APHA promotes the scientific and professional foundation of public health practice and policy, advocates the condition for a healthy society, emphasizes prevention, and enhances the ability of members to promote and protect environmental and community health. Based on the values of health, equity, diversity, empowerment, integrity, dignity, and knowledge for individuals and communities, APHA is the leading professional association that promotes and protects the health of people. Dr. Mohammad Akhter will be testifying for the American Public Health Association.

(2) **The Safe Food Coalition** is an informal group of consumer, public health, whistleblower, senior citizen and labor organizations. It works to educate the public about the hazards of foodborne illness and has sought Congressional and Administrative action to improve meat, poultry and seafood inspection. Member associations include: American Association of Retired Persons, American Public Health Association, Center for Science in the Public Interest, Consumer Federation of America, Environmental Information Center, AFL-CIO, Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, S.T.O.P.-Safe Tables Our Priority, and United Food and Commercial Workers International Union. Because of the diversity of the membership, the Coalition does not take a position on issues of which a consensus is not possible. Carol Tucker Foreman will be testifying on behalf of the Safe Food Coalition.

(3) **Public Voice for Food & Health Policy** is a national, nonprofit research and advocacy organization that looks at food and agriculture policy from a consumer perspective. Public Voice promotes a safer, healthier and more affordable food supply for all Americans. It urges stronger food safety laws and regulations and more informative, understandable nutrition labeling rules and resists congressional efforts for roll back food safety regulations. Bob Hahn will be testifying for Public Voice for Food & Health Policy.

(4) **American Council on Science and Health** (ACSH) is a consumer education consortium concerned with issues related to food, nutrition, chemicals, pharmaceuticals, lifestyle, the environment and health. It is an independent, nonprofit, tax-exempt organization. The nucleus of ACSH is a board of 250 physicians, scientists and policy advisors. Dr. Ruth Kava will be testifying for the American Council on Science & Health.

V. HEARING THEMES

The fourth PSI food safety hearing will focus on identifying ways to improve the food import process. PSI's investigation has found that unsafe food imports enter the U.S. commerce and pose a public health risk to American consumers because federal agencies do not effectively use their existing resources and controls over imported food shipments are weak and inconsistently applied.

Specifically, PSI's investigation found that:

- Safety of imported food is a serious public health problem;
- Food safety measures are insufficient to protect consumers from tainted food; and
- Weaknesses in import procedures are vulnerable to abuse by unscrupulous importers.

During the two-day hearing, we will hear from Members of Congress, representatives from Executive Branch agencies (U.S. Customs Service, Food and Drug Administration, and Food Safety and Inspection Service), and representatives from the private sector, including several industry, consumer, and scientific organizations. Specific issues that will be explored through these witnesses include:

- How to reduce the public health risk to American consumers;
- How to improve the use of existing resources; and
- How to better control imported food shipments.

Senate Permanent Subcommittee on Investigations
EXHIBIT #2

Congressional Research Service • Library of Congress • Washington, D.C. 20540

Memorandum September 21, 1998

TO : Senate Committee on Government Relations
Permanent Subcommittee on Investigations
Attention: Mary Mitschow

FROM : American Law Division

SUBJECT : Safety of Imported Foods: Authority of the Food and Drug Administration and U.S. Department of Agriculture, Food Safety and Inspection Service

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This memorandum responds to your request concerning the jurisdiction and authority of the Food and Drug Administration (FDA)[1] and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) relative to the safety of imported foods. The following provides an overview of the FDA's authority over imported foods and the USDA's authority over imported meat, poultry, and egg products. As requested, the overviews summarize and detail the agencies' statutory and regulatory authorities as they relate to the food imports that come within their respective jurisdictions. In addition, the overviews: summarize the objectives of the statutes involved; summarize the agencies' programs that enforce the statutes; and, highlight similar or different features of the statutes and programs. You requested special attention be given to the differences between USDA's and FDA's range of enforcement tools and overall program framework and how this may affect enforcement. However, as discussed, qualitative judgments about the agencies' discretion in using their enforcement tools and other similar issues that require evaluation or investigation are beyond the scope of this memorandum. Finally, a comprehensive list of statutory and regulatory citations over imported foods is included for your reference.

Overview of Authority of the Food and Drug Administration Over Imported Foods.

Pursuant to the Federal Food, Drug, and Cosmetic Act, as amended[2] (FFDCA), and other relevant statutes, the FDA is charged with protecting the health and safety of the public by ensuring that certain foods, and other articles, are safe and properly labeled. Although primary responsibility for administering the nation's laws relating to imports is given to the

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[1] The Assistant Secretary for Health has redelegated to the Commissioner of the FDA authority found in the Federal Food, Drug, and Cosmetic Act, and other relevant statutes. See, 21 C.F.R. Sec. 5.10.

[2] 21 U.S.C. Secs. 301 et seq.

U.S. Customs Service, an agency within the Department of the Treasury,[3] the FDA is responsible for determining whether or not an article offered for importation is in compliance with the statutes and regulations enforced by the FDA. The FDA ensures the safety of all domestic and imported foods, excluding meat and poultry and some egg products. The agency itself has described its food safety, governmental role:

> FDA ... is responsible for ensuring the safety and wholesomeness of all foods sold in interstate commerce except for meat, poultry and eggs, all of which are under USDA jurisdiction. FDA develops standards for composition, quality, nutrition and safety of foods, including food and color additives. It does research to improve detection and prevention of food contamination. It collects and interprets data on nutrition, food additives and environmental factors, such as pesticides, that affect foods. FDA also sets standards for certain foods and enforces federal regulations on labeling, food and color additives, food sanitation and safety of foods. FDA inspects food plants, imported food products, and feed mills that make feeds containing medications or nutritional supplements for animals destined as food for humans. FDA monitors recalls of unsafe or contaminated foods and can get illegally marketed foods seized.[4]

The Act requires that food sold in interstate commerce, including imported foods, is safe, sanitary, wholesome and properly labeled and that imported foods meet the requirements which govern domestic food. The FFDCA prohibits the introduction or delivery for introduction of any food that is adulterated or misbranded.[5] A food is generally deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health, i.e., filthy, putrid or decomposed substances; pesticide chemical residues[6]; product of diseased animal; prepared or packed under insanitary conditions; etc.[7] A food is generally deemed to be misbranded if its labeling is false or misleading in any particular[8] and the FFDCA prohibits the alteration, mutilation, etc., of the whole or any part of the labeling.[9] Current law authorizes the FDA to halt goods offered for import to prevent the introduction of violative foods into the United States. The FDA's power to stop imports can reach an individual article of food or shipment at the port of entry

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[3] A memorandum of understanding between the FDA and the Customs Service identifies the jurisdiction and roles for each agency. FDA is delegated authority to collect samples, issue notices relating to the samples, and issue other notices as well. Moreover, FDA officers are designated Customs Officers to perform these and other duties. See, MOU, FDA Compliance Policy Guide 7155g.03 (August 14, 1979). The refusal of admission, and subsequent reexportation or destruction of goods is carried out under the direction of Customs. However, at some ports actual supervision of destruction of goods in violation of the law may be conducted by FDA pursuant to a local FDA/Customs agreement. Supervision of reconditioning plans is exercised by either FDA or Customs, as worked out between the agencies. See Reg. Policy Manual, Chap. 9, Subchap. on Import Procedures.

[4] Statement, FDA Food Safety Team, FDA Consumer, July/Aug. 1988.

[5] 21 U.S.C. Sec. 331 [Prohibited Acts].

[6] The EPA issues pesticide tolerances and registers pesticide use, however, the FDA enforces the pesticide tolerances on food articles.

[7] 21 U.S.C. Sec. 342 [Adulterated food].

[8] 21 U.S.C. Sec. 343 [Misbranded food].

[9] 21 U.S.C. Sec. 331 [Prohibited Acts].

or beyond and the agency can "block list" a country's goods or a manufacturer's goods to block entry all together.

To make sure that imported foods meet the same standards as those which apply to domestic foods, the FDA has been delegated an array of enforcement tools and a large degree of discretion in their enforcement approach. Administrative enforcement tools include: warning letters, voluntary recall[10], detention, automatic detention, block listing, emergency permit control[11], re-export and other administrative processes. The FDA may also initiate judicial seizure and condemnation actions, which could lead to destruction of goods, injunctions, and prosecutions.[12] The FDA maintains a computerized system that enables it to perform many of its duties and track imports.

More specifically, the FDA, in coordination with the Customs Service, is authorized and directed to pursue enforcement to ensure compliance with the law and regulations[13]. Based on current statutory provisions, FDA's approach is such that it evaluates food offered for import at a U.S. point of entry. At this point in the importation process, the agencies initiate their compliance and enforcement roles.[14] Current law provides that[15] the Secretary of the Treasury (Customs) is directed to deliver to the Secretary of Health and Human Services (HHS), upon his request, samples of food, and other articles, which are being imported or offered for import into the United States. With respect to foods, if it appears from the examination of the samples or otherwise that (1) the article has been manufactured, processed, or packed under insanitary conditions or (2) the article is forbidden or restricted in sale in the country produced or from which is was exported, or (3) the article is adulterated, misbranded, or in violation of 21 U.S.C. 355, then the article "shall be refused admission," except as provided in subsection (b) of 21 U.S.C. 381. The Secretary of the Treasury is authorized to cause the destruction of any article refused entry unless the article

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[10] Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include market withdrawal or a stock recovery. 21 C.F.R. Sec. 7.3.

[11] Emergency Permit Control enables the FDA to increase enforcement in particular hazard categories. If the FDA finds that there is a potential for injury from products as a result of microbial contamination, and the contamination arises during manufacturing, processing or packing, and the contamination is of a type that is not able to be adequately determined after the products go into the stream of commerce, the FDA can issue a permit control. This, in effect, is a temporary program of licensing individual manufacturing establishments. Compliance with the control and active inspections allow manufacturer to produce and market. The FDA retains a great degree of discretion under this program. See, "Food and Drug Administration," James T. O'Reilly, 2d Ed., Sec. 9.07.

[12] 21 U.S.C. Secs. 332, 333, and 334.

[13] Food regulations and good manufacturing practices are set forth in the Code of Federal Regulations, Title 21. The FDA also issues pertinent compliance policy guides; alerts; manuals and other notices and information.

[14] Coordinated action between the FDA and the Customs Service continues in the rulemaking realm. The law provides: The Secretary of the Treasury and the Secretary of [HHS] shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381...except as otherwise provided.... Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of [HHS] shall determine. 21 U.S.C. Sec. 371.

[15] 21 U.S.C. Sec. 381 [Imports and exports].

is exported, in accordance with regulations, within 90 days of the date of notice of the refusal or within the time permitted under the regulations.

Subsection 381(b) of Title 21, U.S. Code, provides that while the decision on admission of the article is pending, the Secretary of the Treasury may authorize delivery of the article to the owner or consignee, upon execution of a bond providing for the payment of liquidated damages in the event of default. If HHS/FDA determines that the article included within the provisions of section 381(a), clause (b), i.e., the article is adulterated, misbranded or in violation of section 355, can , "by relabeling or other action, be brought into compliance ... or rendered other than a food, ... final determination as to admission ... may be deferred and, upon filing a timely written application by the owner or consignee ...." With the execution of a bond, the Secretary may, in accordance with regulations, authorize the applicant to relabel or take other action specified in the Secretary's authorization. The authorization could include destruction or export of rejected articles or portions of the articles. The relabeling or other action performed under the official authorization must be under the supervision of the program official.[16] All expenses relating to destruction and the supervision of the relabeling or other action authorized and expenses in connection with storage, labor, and other regulatory matters, incurred with respect to an article refused admission, shall be paid by the owner or consignee, and in default of the payment, shall constitute a lien against future imports.

Thus, when foods from exporting countries are presented at ports of entry, the FDA and Customs screen incoming shipments for evidence of *or* the appearance of misbranding or adulteration. Samples are taken on a percentage of the food imports and these samples are collected and analyzed. The FDA is authorized to reject a shipment of imported food based on the appearance of adulteration or a finding of adulteration or misbranding. Under the FFDCA, detention is authorized pending analysis of the samples and inspection. Notice is provided to the importer that a sample was taken and sent for analysis. If a violation is found, a notice of detention and hearing is issued. Current law provides that an importer may "recondition" the articles, if so approved and supervised by the FDA, in order to come into compliance with pertinent laws and regulations. The importer can be required to post a bond, which is forfeited if the goods are not properly reconditioned. Re-exportation of the imported food found to be in noncompliance is authorized under the FFDCA. However, if the agency believes the importer will attempt re-entry, or for other reasons, the FDA may disallow re-exportation and order destruction of the goods to protect the public's health.

FDA's Regulatory Procedures Manual (RPM) sets forth its import procedures. A brief summary of these procedures follows and may provide a checklist of procedures used by officers as food items are offered for importation:

> *Ports covered by the FDA*: Most ports of entry into the U.S. are covered by FDA personnel, acting in cooperation with Customs. The entry is evaluated; additional documentation may be requested; FDA may collect a sample; FDA determines whether all or part of shipment is to be held intact for FDA examination or sampling.[17]

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[16] 21 U.S.C. sec. 381(b).

[17] 19 C.F.R. Sec. 151.4.

Ports not covered by FDA: There are ports where Customs does not maintain electronic entry system and FDA does not cover under a normal operating schedule. The FDA district office coordinates coverage with Customs manager to ensure FDA notification.

Entry sampling: FDA may request an examination or sample of articles under its jurisdiction. If none is taken, the shipment may proceed. If the article is later found to be in violation of the law, the FDA is not prevented from taking legal action, i.e., seizure, injunction, because it allowed admission without examination at point of entry. If examination or sample is requested, FDA notifies Customs and the broker, importer, etc., of its intent to sample. Additional procedures apply.

Notice of sampling: Whenever FDA intends to sample an article offered for import, it issues the Notice of Sampling to importer, consignee, etc.

Payments for samples: The FDA will pay for all physically sampled articles found to be in compliance with the Act and regulations. Also, FDA pays for samples collected in an FDA audit of a sample of goods detained and found to be in compliance. FDA does not pay for samples taken in connection with the supervision of a reconditioning.

Procedure when no violation is found: If the article is in compliance, it is admitted.

Procedures when violation is found: Examination and sampling may indicate that the article appears to be in violation of the law or regulations. If detention is ordered, a "notice of detention and hearing" is issued. The importer may present evidence as to the admissibility of the article and propose a manner in which an article can be brought into compliance or be removed from the Act. FDA may authorize relabeling or other action. After review of the application to relabel or recondition, the FDA will notify the importer of the approval or disapproval.

Inspection after completion of authorization to bring article into compliance: After the relabeling or reconditioning, the applicant submits a certificate or provides notice of completion. FDA may conduct follow-up inspection and verification. A report is made and forwarded to FDA.

Procedure when conditions of authorization have been and have not been fulfilled: If conditions for relabeling or reconditioning are fulfilled, the owner is notified of the admissible portion of the goods. Approval by FDA of goods is made, if appropriate. If conditions have not been fulfilled, the FDA should not consider another request unless the authorization includes a change or adjustment from the original method of relabeling or reconditioning.

Procedure after hearing - Notice of Release: After the hearing on admissibility, the FDA may find the article is not in violation and may be released. The notice indicates that the detained article is no longer subject to detention or refusal of admission.

Procedure after hearing - Refusal of Admission: if articles are found to be in violation, they are refused admission. Notice of decision is made and the FDA states its findings. Notice sent to Customs. If an article is refused admission, it must be destroyed or exported under Customs' supervision within 90 days of receiving the Notice of Refusal or within additional time as specified by Customs. FDA is responsible for the protection of the U.S. public regarding foods, and other articles, and that exists until the violative article is either destroyed or exported.

The RPM sets forth the FDA's enforcement approach. Special provisions and strategies have been developed for problem importers. The following summarizes the agency's enforcement tools:

Warning letters: letters to remind firms of their responsibilities to import articles that are in compliance and to assure that only non-violative articles enter domestic commerce in the U.S. Warning letters may be issued to the importer, consignee, etc., for an importer's failure to provide the FDA with information regarding the availability of sampling or any situation that warrants an official notification before other action relating to compliance is taken.

Reconditioning proposals: Under the Act, when an article is found to be in violation, the importer has the option of exporting it, destroying it, rendering it not subject to the Act, or requesting permission to attempt to bring it into compliance. With respect to "reconditioning" the detained article, the Act provides in 21 U.S.C. Sec. 391(a) that the owner/consignee, in accordance with proper procedures, may bring the article into compliance. The agency uses appropriate controls and sets requirements before approving an application to recondition. Further provisions are set forth.

Requests for voluntary recall: This involves requesting a firm to initiate a voluntary action to recall. The manual indicates that the FDA districts should encourage the firm to consider a voluntary recall (1) when a potential health hazard situation exists or (2) when there is evidence of distribution of detained or refused goods. Publicity, i.e., press coverage, may be pursued in accordance with guidelines. Supervision of returned goods by FDA or Customs must be made. If disposition of the problem goods is destruction, it is suggested that FDA supervise. If articles are exported, FDA or Customs may supervise.

Seizure: This is a method to gain control over the violative imported articles. Seizure is a judicial action against the article. Through laboratory analysis, it must be shown the article was in violation. Seizure is considered for an article which (1) represents a potential health hazard and has been or is likely to be distributed in domestic commerce, (2) has been fraudulently identified/represented in documents submitted to the agency, or (3) is identified by the agency as a refused article. When an article is seized and condemned, it is subject to 21 U.S.C. Sec. 334(d). Certain condemned imported articles may be re-exported under limited circumstances. Re-exportation is not available for foods in violation of the emergency control permit provision in section 344, Title 21. These articles must be destroyed. The law and regulations set forth the procedures for re-exportation.

Injunction: Injunctions curtail the distribution of the goods and may require a pattern of violations with some danger of recurrence.

Citation/Prosecution: This method of enforcement is used when other actions are determined to be inadequate to correct violative practices, or the violation is sufficiently egregious to warrant punishment, e.g., repetitive illegal distribution; false or misleading entry documents; submission of false or misleading private laboratory results, etc. Additionally, charges under Title 18, U.S. Code, may be considered, e.g., obstruction of justice, false statements, smuggling, conspiracy, etc.

It is helpful to discuss more fully some of the procedures and enforcement methods mentioned in the RPM. Detention of violative goods is an important and relatively commonly used enforcement tool for the FDA. Among the reasons for FDA detentions are: filth (insects, rodents), pesticide residues, microbial contamination, labeling, decomposition, mold, heavy metals, noncompliance with low-acid canned food regulations, unapproved additives, and other reasons.[18] Filth in food poses challenging issues for the agency and led the FDA to issue good manufacturing practices (GMPs) in 21 C.F.R. Part 110. The Act defines adulterated food as one that "consists in whole or in part of any filthy, putrid, etc. substance, or is otherwise unfit for food" and one that "bears or contains any poisonous or deleterious substance which may render it injurious to health."[19] Some levels of contaminants in food may be regulated by formal tolerances under 21 U.S.C. Sec. 346 and 21 C.F.R. Part 109 or by less formal action levels, set by the FDA pursuant to 21 U.S.C. Sec. 336. The GMPs clarify what constitutes food adulteration and set forth "action levels." Briefly, the action levels may allow for the presence of a contaminant if it is at an irreducible minimum after all precautions have been taken and the food does not present a hazard. The

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[18] "Food From Developing Countries: Steps To Improve Compliance", 53 Food Drug L. J. 139 (1998).

[19] 21 U.S.C. Sec. 342.

criteria and definitions of these regulations are followed in order to determine whether the food article is in violation of the law and whether enforcement actions will be initiated.

Repeated, consistent problems with a country or food item may prompt the FDA to use automatic detention and "block listing." If the FDA has a series of import problems with a country or food class, it may be added to a "block list" to block the usual entry of the goods. This detention can lead to destruction of the goods or efforts to bring the items into compliance.[20] This procedure entails placing shipments under "detention without physical examination" (DWFE) or automatic detention. This is an administrative function to detain products without physically examining shipments and is based on information or evidence that these articles are hazardous and in violation of the law. All ports are alerted with an import alert to cut off entry. Inspectors are called upon to inspect all shipments or to automatically detain the product until further action is taken. Importers may petition to have their products removed from this category. With appropriate certification, laboratory testing and assurances, the FDA may permit removal from the detention list. Interestingly, a recent law review article notes that some manufacturers do not appear to object to automatic detention status and do not view this as a liability. Rather, detention is a method that helps to prove their legitimacy. For instance, the article states that three of the five Hong Kong mushroom canners are on automatic detention and want to stay there. This distinguishes their mushrooms from other Chinese mushrooms.[21]

When food articles are found to be in violation of the law, an importer may request to reexport his goods, rather than have them destroyed. A recent case illustrates FDA's authority to deny an importer's request to re-export food articles that are either misbranded or adulterated and to order the destruction of the goods after initiating a seizure and condemnation action. In *U.S. v. Food, 2, 998 Cases*[22] the court held that the FDA, under the FFDCA, was authorized to avail itself of the judicial remedy of seizure and condemnation, and order the goods destroyed, as opposed to permitting reexportation. The court stated:

> The legislative history [of the FFDCA] ... makes clear that Congress intended to empower the FDA with the broadest possible authority over imported contaminated goods. The plain words of the statute expansively define `interstate commerce' to effectively include foreign commerce. Moreover, no statutory language prohibits the application of [section] 334 to goods seized at the port of entry....When the government lacks the ability to prove a violation of the FFDCA by a preponderance of the evidence, or when the risks to human health are not major or critical, the government can pursue the administrative procedures of section 381 and simply require reexportation of the goods. ... On the other hand, when the circumstances pose a critical risk to the health of United States citizens, the FDA has the option of initiating a judicial condemnation proceeding under section 334.[23]

The court held that the FDA is authorized to destroy the goods without giving the importer the opportunity to reexport, but only after proving, by a preponderance of the evidence, that

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[20] "Food and Drug Administration", James T. O'Reilly, 2d. Ed., Sec. 9.06 [Imported Foods].

[21] 53 Food Drug L. J. 139, 145 (1998).

[22] 64 F.3d 984 (5th Cir. 1995).

[23] Id., at p. 992.

the goods were adulterated or misbranded. This allows the government a "sure mechanism"[24] to prevent the possibility of undetected reimportation of dangerous goods into the United States. This case underscores the FDA's enforcement authority to initiate seizure and condemnation proceedings when goods are seized at the port of entry and to order destruction in order to protect the public health.

Foods that have microbial contamination that may be injurious to health trigger emergency permit controls.[25] The FDA is authorized to issue permits that attach conditions governing the manufacture, processing or packing of this class of food, for a temporary period, to protect the public health. During this period, no person may introduce or deliver into commerce any food that unless he holds an official permit. The law provides that a permit may be suspended if it is found that the conditions were violated and the FDA has access to the permit-holding establishment to ascertain whether the conditions are being met.

Voluntary recall is an enforcement tool used to remove or correct consumer products that are in violation of the law. Recall is a voluntary action that takes place because manufacturers and distributors are responsible for protecting the public health from products that present a risk of injury or gross deception or are otherwise defective.[26] At any time, recall may be undertaken voluntarily by manufacturers and distributors or at the request of the FDA. It is viewed as more appropriate and affording better protection for consumers than seizure, when many of the products have been widely distributed. "Seizure, multiple seizure, or other court action is indicated when a firm refuses to undertake a recall requested by the [FDA], or where the agency has reason to believe that a recall would not be effective, determines that a recall is ineffective, or discovers that a violation is continuing."[27] An evaluation of the health hazard is performed by an ad hoc health hazards committee of FDA scientists and a recall strategy is defined. A recall strategy addresses: the depth of the recall, i.e., specifying where the recall will take effect in the chain of distribution; public warning; and effectiveness checks. In more detail, the regulations set forth and clarify actions related to FDA initiated and company initiated recalls, recall communications, public notices, recall status reports, and termination of a recall.

Overview of Authority of USDA and FSIS, over imported foods.

The Food Safety and Inspection Service (FSIS) in USDA, regulates meat, poultry and shell eggs/products and ensures that these products sold for human consumption are safe, wholesome and properly marked, labeled and packaged. The FSIS administers and enforces the Federal Meat Inspection Act (FMIA)[28], the Poultry Products Inspection Act (PPIA)[29], and the Egg Products Inspection Act (EPIA). A meat or poultry product is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. Where the substance is not an added substance, the article shall not be considered adulterated

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[24] Id., at p. 993.

[25] 21 U.S.C. Sec. 344 [Emergency Permit Control].

[26] 21 C.F.R. Sec. 7.40 [Recall policy].

[27] Id.

[28] 21 U.S.C. Secs. 601 et seq.

[29] 21 U.S.C. Secs. 451 et seq.

if the quantity does not ordinarily render it injurious to health. These substances include pesticides, animal drug residues, or environmental contaminants above set tolerances. Among other things, a product is misbranded if its labeling is false or misleading in any particular.[30] Both the meat and poultry statutes require that imported meat and poultry be produced under inspection systems that are at least equivalent to standards for U.S. products. "Imported products must meet inspection, sanitary, quality, species verification, and residue standards applied to domestic meat and poultry."[31]

Specifically, the Act provides, in part, that no carcasses, parts of carcasses, meat or meat food products of cattle, sheep, etc., shall be imported into the U.S. if such articles are adulterated or misbranded and unless they comply with all the inspection, building construction standards and all other provisions of law and regulations applicable to such articles in commerce in the United States. Moreover, no such articles shall be imported into the U.S. unless the livestock from which they were produced was slaughtered and handled in connection with slaughter in accordance with 7 U.S.C. Secs.1901-1906. Carcasses, parts, etc. may not be imported into the U.S. unless they have been slaughtered and prepared only in foreign plants that are the same as U.S. federally inspected plants. If a country wants to export to the United States, the FSIS makes a thorough evaluation of the foreign inspection system to assure that it is equal to U.S. inspection requirements. This equivalency includes sufficient organizational structure and staffing; ultimate control and supervision by the national government over the official activities of all employees or licensees; qualified, competent inspectors; antemortem inspection; postmortem inspection; a Hazard Analysis and Critical Control Point (HACCP) system; and other important features. The equivalency determination is the threshold issue when establishing eligibility of the foreign country for importation of products into the United States. The foreign country must certify that its establishments comply. U.S. personnel review all foreign systems and plants and report their findings on an annual basis. Eligibility is revoked if the foreign establishment or the country does not comply with applicable laws and regulations.

Further, FSIS inspects, before and after slaughter, birds and animals intended for human food and verifies further processing of meat and poultry products; inspects, before and after breaking, eggs intended for processing and use in human food; provides pathological, microbiological, chemical and other types of scientific examination of meat, poultry and egg products for disease, infection, extraneous materials, drug and other chemical residues, or other kinds of adulteration; conducts emergency responses, including retention, detention or voluntary recall of these products; conducts epidemiological investigations; and, develops cooperative strategies to prevent health hazards associated with animal production practices, and other notable functions.[32]

FMIA mandates a multi-dimensional inspection program that uses random sampling, random inspections, and compliance monitoring sampling and inspections. Imports are subject to inspection, sanitary, species verification and residue standards applied to products produced

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[30] 21 U.S.C. Sec. 601.

[31] "Food Safety...", GAO-RCED-94-192, Sept. 1994, p. 16.

[32] See "Meat and Poultry Inspection, 1996 Report of the Sec. of Agric. to the U.S. Congress, USDA, FSIS.

domestically.[33] Specifically, the statute requires that in order to prevent the use in commerce of meat and meat products which are adulterated, the Secretary shall cause to be made by inspectors, an examination and inspection of all cattle, swine, etc., before they shall be allowed to enter into any slaughtering, packing, meat-canning or other similar establishment. Meat that has symptoms of disease shall be set apart and slaughtered and carefully examined and inspected. Additionally, post mortem examination of carcasses is required. Specific marking and labeling requirements must be met. The law provides that for carcasses that are inspected and condemned, destruction is required in most circumstances. Similarly, under the PPIA, the FSIS is required to inspect any domesticated bird being processed for human consumption, e.g., chickens, turkeys, etc. FSIS also offers a voluntary inspection service (for a fee) for other animals.

Each foreign country that seeks to export to the U.S. must obtain a certification issued by the Secretary stating that the country maintains a program that uses reliable analytical methods to ensure compliance with U.S. standards. The exporting country's system must include qualified inspectors with the authority to enforce national food safety laws and regulations; administrative and technical support for the inspectors; and, inspection, sanitation, quality, microbiological and residues standards equivalent to U.S. standards.[34] The Secretary is required to periodically review the certifications and may revoke them, if appropriate. Besides evaluating the foreign country's inspection system, the FSIS authority includes the inspection of individual establishments to ensure the foreign inspection program is meeting U.S. standards.

In addition to the foreign inspections and certification, all imported meat is held at the point of entry and is reinspected by federal inspectors before it is allowed to enter. If the products meet the U.S. standards, after reinspection, the products may be cleared for entry into domestic commerce. The regulations state: "No product ... shall be admitted ... if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product."[35] The point of entry inspection system is computerized and enhances the inspectors' ability to conduct random sampling and surveillance sampling, to ensure compliance.[36] Every lot is routinely given a visual inspection and checked for certification and labeling compliance. All products required to be inspected are inspected only at an official establishment or at an official import inspection facility *approved* by FSIS. No product required to be inspected may be moved from any port to any place other than a designated location. Program inspectors may take samples, at no cost to the United States, for laboratory examination.[37] If compliance is satisfactory, the products are marked and shall enter the U.S. Products that are inspected and rejected are marked "U.S. Refused Entry." The inspector requests the Director of Customs to refuse admission and direct that it be exported by the owner/consignee within the time specified, unless it is destroyed, and supervised by a program employee, or converted into animal food. An importer refused entry for misbranding may bring the product into compliance, under the

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[33] 21 U.S.C. Sec. 620.

[34] See regulations which detail the equivalency and inspection programs. 21 C.F.R. Part 327.

[35] 9 C.F.R. Sec. 327.3.

[36] Several limited exemptions from inspections exist. See, 9 C.F.R. Part 303.

[37] Special provisions apply to imports from Canada.

supervision of program officials. No product that is refused entry and exported to another country may return the product to the United States. Any product returned shall be subject to administrative detention and seizure/condemnation procedures as well.

The FMIA is enforced by various criminal penalties and civil administrative sanctions and procedures.[38] Civil sanctions include seizure and condemnation and injunction which are initiated by filing of an action in a U.S. district court. The court has the authority to order that the article be destroyed, be returned under certain conditions, or be sold. At the same time, FSIS is authorized to detain the articles and exercise its range of enforcement power as is required or within its discretionary authority. If the article is condemned, the law provides that it can be distributed, destroyed, or sold, in accordance with 21 U.S.C. Sec. 673. By pursuing an injunction, the Act provides that U.S. courts are vested with authority to enforce the Act and to prevent and restrain violations.[39]

With regard to criminal penalties, the Act provides that any person, firm or corporation who violates the law for which no other criminal penalty is provided shall upon conviction be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both. If the violation involves intent to defraud, or any distribution or attempted distribution of an adulterated articles, except as provided in the law, the violator shall be subject to imprisonment for not more than three years or a fine of not more than $10,000 or both. Certain exceptions are made for persons who in good faith receive for transportation violative articles. Minor violations are handled with discretion by the Secretary and the Act does not require the Secretary to report for prosecution violations of this degree if he believes the public interest will be adequately served by a suitable written warning. The Act also contains provisions relating to bribery and assault and make applicable other statutory provisions relating to subpoenas, records, reports, etc.

Additional administrative sanctions empower the agency to ensure compliance. For example, as noted above, the agency approves of inspection service facilities. The FSIS monitors these facilities and may withdraw or deny this approval, i.e, unfit to perform functions, conviction of felony based on handling unwholesome or misbranded food, etc. Also, inspectors are authorized to have immediate access to all parts of the inspected establishment at any time and at other times when due notice is given. Access to related industries and businesses is also authorized. Record-keeping and reporting requirements apply to inspected establishments and aid the agency in performing its functions. And, the Secretary is expressly authorized to promulgate rules to implement the Act.

The FSIS also enforces the Poultry Products Inspection Act (PPIA).[40] Similar to meat products, the objective of the Act is to ensure that poultry products are wholesome, not adulterated, and properly labeled, marked and packaged. The program is inspection-based and enforcement focuses on preventing the introduction and/or movement or sale of adulterated or misbranded products in domestic commerce.[41] With regard to imported poultry products,

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[38] For a full discussion of sanctions, see "Agricultural Law", Harl, Vol. 9, Sec. 65.

[39] 21 U.S.C. Sec. 674.

[40] 21 U.S.C. Secs. 451 et seq.

[41] In part, the statute provides that "adulterated" means if the poultry product bears or contains

(continued...)

the statute provides that no slaughtered poultry, or parts, of any kind shall be imported into the United States unless they comply with applicable law and regulation. All poultry (including parts and products), capable of use as human food offered for importation into the U.S. must be subject to inspection, sanitary, quality species verification and residue standards that achieve a level of sanitary protection equivalent to that achieved under United States standards; and have been processed in facilities under conditions that achieve a level of sanitary protection equivalent to that achieved under U.S. standards.[42]

The Secretary enforces these provisions through a mandatory inspection program which includes random inspections and compliance-monitoring sampling and inspection. Similar to FMIA provisions, inspection services are approved and perform inspection functions. The Secretary is authorized to withdraw or deny the approval of the inspection service, in accordance with the statute and regulations. All products found to be adulterated must be condemned and, if no appeal is taken, destroyed for purposes of human food. In some cases, the product may be reprocessed. Multi-step procedures for antemortem and postmortem inspections are followed to ensure wholesomeness. The process is similar to that in place for imported meat products. For poultry imports, the FSIS determines whether the foreign maintains an equivalent inspection system and may certify that country for importing its products into the U.S. The evaluation is conducted by FSIS according to criteria set forth in 9 C.F.R. 381.196. If appropriate, certification is made, and can also be revoked. Inspections take place in the foreign establishment and at the point of entry. Violative articles are refused entry and must be destroyed or reexported in accordance with the law and regulations. Detention is authorized, as is judicial seizure and condemnation proceedings. The Act specifies various actions that are prohibited which may lead to criminal penalty, e.g., bribery, assault, acts committed with a dangerous weapon, etc. Moreover, with respect to labeling and misbranding provisions, the Secretary regulates the labeling of poultry products and all products must bear proper labeling.

The Egg Products Inspection Act (EPIA)[43] was enacted to protect consumers, the public health, and the public welfare by assuring that eggs and egg products (hereinafter eggs) are safe and wholesome and provide an environment conducive to the health of the shell egg industry and egg products industry. The statute creates a federal program with continuous inspection at processing plants; that prohibits improper disposal of eggs which could pose a health problem and impermissible use of eggs in the preparation of human food; and creates standards and labeling requirements. The Act seeks to prevent the movement or sale for human food, eggs or egg products that are adulterated or misbranded. "Adulteration" applies, among other things, if the product bears or contains any poisonous or deleterious substance which may render it injurious to health. "Misbranded" applies to such products which are not labeled and packaged in accordance with the Secretary's regulations.

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[41](...continued)
any poisonous or deleterious substance which may render it injurious to health. The term "misbranded" applies when the product's label is false or misleading in any particular; is offered for sale under the name of another food, etc. See, 21 U.S.C. Sec. 453 [Definitions].

[42] 21 U.S.C. Sec. 466 [Imports]. Special provisions apply to Mexico and Canada.

[43] 21 U.S.C. Secs. 1031 et seq.

USDA's jurisdiction covers shell eggs, egg products, egg products not intended for humans and imported eggs and egg products. Again, this program is inspection-based and provides additional requirements for imports. Before entry into the U.S., eggs and egg products must satisfy processing, labeling and packaging requirements. The statute provides, in part, that no restricted eggs capable of use as human food shall be imported except as authorized by the Secretary. No egg products capable of use as human food shall be imported into the U.S. unless they were processed under an approved continuous inspection system of the government of the foreign country of origin and are labeled and comply with U.S. regulations. Violations may lead to detention, seizure and condemnation and destruction or sale. Some acts may lead to criminal penalties. Prohibited acts that are noncriminal in nature may lead to fines. Moreover, administrative sanctions, similar to those discussed above, empower the Secretary to enforce the EPIA.

Discussion of differences and similarities of FDA and FSIS systems and discussion regarding possible changes to current law that could strengthen or equalize statutes.

Numerous issues concerning the FDA and FSIS systems could be raised. We have attempted to address specific concerns of interest to you as well as other issues that appear to relate to these concerns. The following addresses statutory and regulatory provisions that appear to affect or mandate the type of the enforcement approach followed by FSIS and FDA. We have not attempted to address issues that require a judgment as to how well the agencies are performing their functions. Investigations concerning the number of inspections conducted; percentage of shipments inspected; resource constraints; personnel issues, etc., or evaluations of effectiveness of the programs are beyond the scope of this memorandum.

1. GAO has reported, and to varying degrees, others have agreed, that the FFDCA does not provide the FDA with enforcement authorities that are as powerful as those authorities directing USDA's enforcement efforts. [44] Obvious similarities exist in the overall mission of the FDA and FSIS and their food safety objectives: to protect the public health and prevent the introduction into commerce adulterated or misbranded foods. A general comparison of the two systems shows that the FDA system is such that decisions relative to imports are made at the point of entry. Under FDA's jurisdiction, the arrival of food imports are not *preceded* by a certification and inspection program as is the case with FSIS. The FDA must rely on voluntary agreements with exporting countries to comply with U.S. food standards. In contrast, USDA has the authority to review and certify that an exporting country's meat inspection system is equivalent to the U.S. system, before the country can ship products to the United States. FSIS has in place an equivalency system that certifies that imports comply with domestic standards for wholesomeness, sanitation, labeling and other important features.

To a certain extent, and within the scope of its statutory authority, FDA uses block listing and import alerts as pre-entry types of administrative actions, however, most shipments are attended to at the point of entry. However, its statutory authority limits its jurisdiction to point-of-entry regulation. In contrast, the USDA system is inspection-based and calls for certification and evaluation of exporters (or potential exporters) well before food items arrive at the U.S. port of entry. The "equivalency" system provides the agency with broad enforcement authority. The inspection teams are sent to foreign countries and foreign establishments to perform evaluative and certification processes. Only with pre-certification

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[44] "Food Safety: Changes Needed ...," GAO/RCED-94-192, Sept., 1994, p. 54.

can a foreign country export to the U.S. The inspection system is multi-faceted, with various types of random and planned inspections and sampling. Moreover, at the point of entry, U.S. officials reinspect the goods offered for importation. The reinspection provides another important stop-gap measure that is aimed at preventing the introduction of adulterated or misbranded food.

Recently, GAO reported: "Federal agencies cannot ensure that the growing volume of imported foods is safe for consumers."[45] GAO emphasized that the FDA approach is ineffective in protecting the public's health and called for a system based on equivalency, similar to that employed by FSIS. The GAO report noted that FDA's approach does not ensure that foods are produced under adequately controlled conditions; that FDA inspects only 2 percent of all foreign shipments; and, inspections will not detect some organisms for which visual inspections and lab tests are inadequate. In contrast, as provided for in statute and regulations, FSIS enforces the law by placing the burden on exporting countries to maintain a system that is equivalent to U.S. standards. Given its current statutory authorization and underlying regulations, the port of entry system continues to be FDA's approach. To bring relative parity to the agencies in their enforcement authority, it would appear that Congress would need to enact a rather comprehensive bill to modify and strengthen the FDA's authority. Perhaps not all features of the FSIS system would make sense for FDA. Indeed, the FDA appears to favor an equivalency program, but does not currently support a mandatory equivalency program. FDA has commented that mandatory equivalency agreements as a precondition to entry "could have the undesirable effect of forcing FDA to bar entry to imports from most of the world until such time as the Agency could make a determination of equivalency." [46] The agency continued:

> [This would require] a process done on a country-by-country basis, and potentially a product-by-product basis. In contrast, the Administration's proposed import legislation...would give FDA the authority to deny entry to a food product that has been prepared, packed, or held under conditions, or subject to systems or measures that do not meet U.S. food safety requirements or otherwise achieve the U.S. level of protection. The legislation would not require that FDA have evaluated such systems, conditions, or measures and made an equivalency determination as a condition precedent to entry of imports.[47]

In addition to perceived weakness in FDA's system, according to GAO, multiple agencies share responsibility for ensuring the nation's food supply. A recent report indicates that 12 different agencies in six federal entities are involved. Thus it appears that a comprehensive legislative framework meant to coordinate and improve food safety efforts would need to go beyond FDA and FSIS, and reach agencies within USDA, Customs, Center for Disease Control and others with food safety responsibilities. Current efforts to improve the system include the President's food safety initiative and Council on Food Safety. However, as GAO reports, "the initiatives do not address the fundamental problem of the system -- its

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[45] "Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable", GAO/RCED-98-103, April, 1998, p. 3.

[46] "Food Safety: Federal Efforts...," GAO/RCED-98-103, April, 1998, p. 53, FDA Comments.

[47] Id., pp. 53-54.

fragmented structure."[48] It would appear that a legislative enactment would be required to amend or supercede existing law in order to create a more centralized, uniform system. Furthermore, extensive rulemaking would most likely follow so that the agencies could promulgate new rules to implement the new system.

2. The FDA authority does not mandate certain features that would increase control over imported goods when first presented at the port. Articles are often left in the hands of importers, although the FDA retains authority to order those items to be made available for inspection or action. The FDA does not maintain control over imports in a warehouse system, as seen with FSIS' imports. Control over the goods at the point of entry appears to raise serious questions and concerns. GAO reported that FDA fails to maintain adequate control over products and shipments to ensure that they are not adulterated or misbranded. It concluded that some shipments enter the stream of domestic commerce before FDA has officially released these items. For instance, a recent report stated that "FDA-regulated foods are not controlled prior to inspection and release...."[49] The report concluded that an investigation showed that "At ports we visited, imported food shipments under FDA's jurisdiction often entered U.S. commerce before being delivered to FDA for inspection or were not properly disposed of when refused entry."[50] Food imports are not placed in FDA-controlled warehouses, as seems to be the case with FSIS warehouses. Additional statutory authority would enable the FDA to maintain control over the imports and ensure, to the fullest extent possible, that the goods are not adulterated or misbranded and would not enter domestic commerce. The statute does not expressly call for such warehouse control, thus amending the law could address these concerns directly. However, the statute provides for the withdrawal or denial of inspection service status for those businesses that prove to be unfit to perform this function, e.g., insanitary conditions, improper disposal of food, etc. In contrast, USDA places imports in FSIS warehouses and segregates violative shipments by placing them in controlled areas. The agency's authority follows through to final disposition.

If imported foods are refused entry into the U.S., the Customs Service is responsible for ensuring that the food product is either reexported or destroyed. Customs may penalize importers for not completing final disposition. To the extent Customs is authorized to follow-through and order final disposal, the FDA is not able to exercise authority and ensure that the final treatment for the violative articles was appropriate and carried out. However, at the same time, it should be noted that under current law, release into commerce does not remove the FDA's authority to reach violative food imports. The FDA is empowered to use the full range of its enforcement authority to bring importers and food articles into compliance and to protect the public health, e.g., seizure and condemnation, prosecution, criminal penalties. etc. It would appear that additional statutory authority could empower the FDA to maintain or retain control over imports and continue to exert authority until final disposition, e.g., reexport, destruction, etc.

A related point involves the current approach which permits importers to enter into bond agreements and retain control over their articles. Some see the bond arrangement, although authorized by law, as not protecting the public health to the full extent possible. The FDA

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[48] Id., p. 9.

[49] GAO report, April 1998, p. 39.

[50] Id., at p. 40.

requires a bond agreement from importers which requires the payment of duties, taxes and charges; requires the importer to retain control over the shipment; and dispose of it if found to be in violation. The bond amount may be inadequate to enforce the law, to the fullest extent possible. GAO points out that when an importer does not comply with the bond agreement, the collection of damages by Customs is often uneven and uncertain.[51] Also, civil money penalty provisions could be added to the overall scheme to, perhaps, deter importers from violating the law and procedures and penalize those that are shown to be violators.

3. You raised questions concerning the validity of private laboratory testing which is sought by importers of detained goods. As noted in the foregoing, FDA is authorized to detain shipments and importers are permitted to present evidence with regard to the shipment, with the intent to show compliance. Private laboratories are used to analyze evidence on behalf of the importer. Current law does not expressly require the use of private laboratories to ensure fairness and scientific objectivity. However, it should be noted that the submission of false or misleading private laboratory results may be prosecuted. Additionally, charges under Title 18, U.S. Code, may be considered, e.g., obstruction of justice, false statements, smuggling, conspiracy, etc.

Notwithstanding that point, administratively, some object to the use of private laboratories to show that the item is in compliance. As an alternative, administratively, the FDA could place additional requirements on the use of and reliance on private laboratories.[52] Or, Congress may choose to enact legislation to codify more stringent and effective requirements for the use of private laboratories. Through codification, Congress may require an accreditation process so that certain labs are used that have a track record of credibility and objectivity. Such a program would most likely grant FDA the authority to remove a laboratory from the accreditation list if the circumstances warranted it. Also, such a program could include civil penalties for violations, including serious or continuous violations.

4. As noted in the FDA's Regulatory Procedure Manual, not all ports have FDA inspectors. Some say this may encourage importers to "port shop." GAO noted that there are only 35 permissible ports of entry for foods under FSIS control while foods within FDA's jurisdiction may come in through 330 ports of entry. An increase in FDA inspectors or additional coordination with the U.S. Customs Service may cut off an importer's effort to circumvent FDA enforcement. Express statutory and regulatory provisions could require FDA inspectors to officially supervise more ports of entry, if not all. Available resources is an ongoing issue with direct impact on the number of inspectors available to perform the inspection function. Changes in the number of inspectors at ports of entry would necessitate increases in funding or the realignment of funding, if possible.

5. Another concern you expressed relates to importers who seek to "recondition" articles which have been refused entry in order to bring them into compliance. In brief, under current FDA law, when an article is found to be in violation, the importer has the option of exporting it, destroying it, rendering it not subject to the Act, or requesting permission to attempt to bring it into compliance. With respect to "reconditioning" the detained article, the Act provides in 21 U.S.C. Sec. 391(a) that the owner/consignee, in accordance with proper

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[51] GAO/RCED-94-192, Sept. 1994, p. 55.

[52] FDA indicates that it has issued new guidance on laboratories and verification of results. See GAO Report, April 1998, p. 52, Comments from FDA.

procedures, may bring the article into compliance. The agency is required to use appropriate controls and set requirements (1) before approving an application to recondition and (2) to ensure the proper reconditioning has taken place. Some may object to the option of "reconditioning" after the agency has refused entry for the articles. Again, related problems associated with importers using private laboratories not regulated or certified by the FDA may add to difficulties in FDA's oversight of the reconditioning process. To change or remove this option for the importer, Congress would be required to enact a statutory amendment. Flowing from that, the agency, presumably, could promulgate regulations that reflect and implement Congress' new requirements.

6. With reference to USDA's inspection system, under the FMIA and PPIA, antemortem and postmortem inspections are required. However, the laws do not expressly state how the inspections are to be made or what the program should include. FSIS developed the carcass-by-carcass and daily inspection system. GAO has recommended changes in this system and questions whether this approach is cost-effective. This system has been developed administratively and may be modified in the same manner to improve overall effectiveness or adjust to different objectives or resource constraints. Or, an alternative could include statutory changes that require a particular type and method of inspection. FSIS noted in a recent GAO report that the statutes are silent on the type of inspections and the daily inspection process.[53] Thus, changes to inspections may be mandated by statute (or statutory amendment) or changes in rulemaking. Also, should an omnibus piece of legislation be enacted that would consolidate various agency food safety functions, changes to current inspection practices in USDA, particularly in light of resource constraints, may be considered.

In conclusion, numerous issues relating to FSIS and FDA authority over food imports exist. The overviews of the statutory and regulatory authorities of the agencies indicate the overall scope of their authority; the approach that Congress has chosen for the agencies; and differences and similarities in the overall framework. The foregoing identifies some ongoing concerns and indicates possible statutory or regulatory changes that may serve to strengthen the import system and perhaps establish an approach at FDA similar to that established for FSIS. Other matters concerning resources, personnel constraints, and perceived weaknesses in current law could be discussed further. Ongoing investigations by GAO and others have shed light on these issues. We have attempted to highlight issues that Congress may address statutorily in legislative action. Full implementation of Congress' legislative goals would entail extensive rulemaking would follow enactment of such a law. In the statute, Congress can offer detailed guidance to the agencies and require certain features to be present in the final rule. Also, Congress can delegate broad authority in rulemaking to the FDA and other agencies in reliance on the agencies' expertise and unique functions.

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[53] "Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness", GAO/RCED-98-224, Comments from USDA, Aug. 1998, p. 38.

Other agencies with food safety responsibilities:

The Food and Drug Administration, FDA
Center for Disease Control, CDC
Food Safety and Inspection Service, USDA, FSIS
Animal and Plant Health Inspection Service, USDA, APHIS
Grain Inspection, Packers and Stockyards Administration, USDA, GIPSA
Agricultural Marketing Service, USDA, AMS
Agricultural Research Service, USDA, ARS
National Marine Fisheries Service, NMFS
Environmental Protection Agency, EPA
Federal Trade Commission, FTC
U.S. Customs Service, Dept. Of the Treasury
Bureau of Alcohol, Tobacco and Firearms, BATF

List of regulations for the FSIS and FDA for food imports:
(We attempted to group the regulations for the FDA and FSIS)

21 C.F.R. Part 1, Enforcement FFDCA and FPLA
21 C.F.R. Part 3, Product jurisdiction
21 C.F.R. Part 7, Enforcement, recall guidelines
21 C.F.R. Part 5, Delegations of authority and organization
21 C.F.R. Part 17, Civil money penalties
21 C.F.R. Part 19, Employee standards of conduct and conflicts of interest
45 C.F.R. Part 73a, Standards of conduct, supplement
21 C.F.R. Part 10, Administrative practice and procedure
21 C.F.R. Parts 70-74, Color additives
21 C.F.R. Part 80, Color additives, certification
21 C.F.R. Part 81, Color additives
21 C.F.R. Part 82, Color additives, listed colors and specifications
21 C.F.R. Part 100, Administrative rulings

21 C.F.R. Part 102, Common or usual names, seafoods
21 C.F.R. Part 161, Fish and shellfish standards
50 C.F.R. Part 260, Inspection and certification
50 C.F.R. Part 261, U.S. standards for grades

9 C.F.R. Part 301, Definitions
9 C.F.R. Part 302, Application of inspection, other requirements
9 C.F.R. Part 303, Exemptions
9 C.F.R. Part 304, Application for inspection, grant or refusal
9 C.F.R. Part 305, Official numbers
9 C.F.R. Part 306, Assignment and authorities, program employees
9 C.F.R. Part 307, Facilities
9 C.F.R. Part 308, Sanitation
9 C.F.R. Part 309, Antemortem inspection
9 C.F.R. Part 310, Postmortem inspection
9 C.F.R. Part 311, Disposal
9 C.F.R. Part 312, Official marks
9 C.F.R. Part 313, Humane slaughter

9 C.F.R. Part 314, Handling and disposal
9 C.F.R. Part 315, Rendering or other disposal of carcasses
9 C.F.R. Part 316, Marking products
9 C.F.R. Part 317, Labeling, marking devices, and containers
9 C.F.R. Part 318, Entry into establishments
9 C.F.R. Part 319, Definitions and standards of identity
9 C.F.R. Part 320, Records, registration, reports
9 C.F.R. Part 321, Cooperation with States and territories
9 C.F.R. Part 322, Exports
9 C.F.R. Part 325, Transportation
9 C.F.R. Part 327, Imported products
9 C.F.R. Part 329, Detention, seizure and condemnation, criminal offenses
9 C.F.R. Part 331, Special provisions
9 C.F.R. Part 335, Rules of practice
9 C.F.R. Part 350, Special services (Voluntary inspection and certification...)
9 C.F.R. Part 351, Certification
9 C.F.R. Part 352, Exotic animals
9 C.F.R. Part 354, Voluntary inspection, rabbits
9 C.F.R. Part 355, Certified products for dogs, etc.
9 C.F.R. Part 362, Voluntary poultry inspection
9 C.F.R. Part 381, Mandatory poultry inspection
9 C.F.R. Part 390, FOIA
9 C.F.R. Part 391, Fees and charges
9 C.F.R. Part 416, Sanitation
9 C.F.R. Part 417, HACCP

7 C.F.R. Part Part 0, Employee responsibilities and conduct
7 C.F.R. Part 1, Administrative regulations
7 C.F.R. Part Part 1a, Law enforcement authorities
7 C.F.R. Part Part 6, Import quotas and fees
7 C.F.R. Part Part 11, National Appeals Division, rules of procedure
7 C.F.R. Part Parts 2610, 2620, Inspector General
7 C.F.R. Part 54, Meat grading, etc
7 C.F.R. Part 55, Voluntary inspection, eggs
7 C.F.R. Part 59, Inspection of eggs and egg products
7 C.F.R. Part 56, Grading of shell eggs
7 C.F.R. Part 70, Poultry and rabbit products, grading, etc.
21 C.F.R. Part 179, Irradiation
21 C.F.R. Part 113, Thermal processing
21 C.F.R. Part 109 Unavoidable contaminants
21 C.F.R. Part 108 Emergency permit control
21 C.F.R. Part 110, Human food, GMP
21 C.F.R. Part 1250, Sanitation in interstate conveyance

21 C.F.R. Part 174-179, Indirect food additives
21 C.F.R. Part 181, Food additives; Prior sanctioned food ingredients
21 C.F.R. Part 182, Substances generally recognized as safe
21 C.F.R. Part 186, Indirect food substance, GRAS
21 C.F.R. Part 189, Substances prohibited from use in human food

7 C.F.R. Part 42, 43, Food container standards

Customs Service:

19 C.F.R. Part 177, Administrative rulings
19 C.F.R. Part 113, Bonds
19 C.F.R. Part 123, Relations with Canada and Mexico
19 C.F.R. Part 19, Warehouses
19 C.F.R. Part 141, Entry of imported merchandise
19 C.F.R. Part 142, Entry process
19 C.F.R. Part 151, Examination, sampling, testing, etc.
19 C.F.R. Part 101, General authority
19 C.F.R. Part 161, Enforcement provisions
19 C.F.R. Part 11, Packing, stamping, markings
19 C.F.R. Part 162, Recordkeeping, inspection, search, and seizure
19 C.F.R. Part 144, Warehouses

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 3
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CRS Report for Congress

The Safety of Imported Foods: The Federal Role and Issues Before Congress

October 14, 1998

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Congressional Research Service • The Library of Congress

ABSTRACT

This report presents a number of policy issues that are under debate in the U.S. Congress regarding how to improve the system governing the safety of imported foods. Issues discussed relate to whether the federal agencies need more resources, whether the Food and Drug Administration (FDA) should have authority to contract specific international agreements, whether there should be more or different enforcement tools or penalties, whether monitoring imported foods for microbial pathogens and pesticide residues is ensuring that imported food is safe, whether imported seafood is being monitored adequately and complies with new U.S. regulations, whether food imports should be labeled as to country of origin, and whether federal food safety functions should be reorganized into one organization. The report contains several appendixes which outline FDA's food safety regulatory system for food imports, and a brief explanation of international agreements and the Codex Alimentarius Commission system for setting food safety standards. This product will be updated periodically. See also CRS Issue Brief 98009, *Food Safety Issues in the 105th Congress*.

The Safety of Imported Foods: The Federal Role and Issues Before Congress

Summary

It is unclear whether imported foods are less safe than domestically produced foods. Illnesses caused by pathogens found in all types of food are a public health problem. With increases in the number of imported food shipments and limited resources for border inspections, however, Congress has begun addressing whether the current system for inspecting and monitoring import shipments is sufficient to protect U.S. consumers.

Two agencies, the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) hold most of the responsibility for ensuring the safety of imported food. Federal laws mandate that all food, produced domestically or imported, must be wholesome, safe to eat, produced under sanitary conditions, and truthfully labeled. Both agencies have computerized systems that track food import shipments at the border. One agency within USDA, the Food Safety and Inspection Service (FSIS), allows imports of meat and poultry only if these products have been produced and processed by a food safety system in the exporting country which is equivalent to that of the United States. FDA, on the other hand, has an import system which is highly dependent on sampling and testing at the border to ensure that the foods are not adulterated or misbranded.

The President's Food Safety Initiative began several coordinated efforts among federal agencies to prevent or contain foodborne illnesses caused by pathogens found in food, both domestically produced and imported. For fiscal year (FY) 1999, Congress appropriated $257 million, $52 million over the FY 1998 appropriations, for efforts that may allow for some expansion of import inspections. Congress also has before it a proposal to charge user fees that could pay for some inspections.

Congress is also debating several bills that would authorize FDA to enter into "equivalency" agreements with trading partners. These agreements are similar to those that USDA now has for meat and poultry imports with 37 trading partners. These bills would authorize FDA to ensure that foreign food safety systems achieve the same level of protection or safety as in the United States. Congress is also considering whether the systems for enforcement and penalties act as a deterrent to fraud and abuse of the import system. Some have suggested that FDA be given authority to levy a full range of penalties against importers violating the standards mandated by the Federal Food, Drug, and Cosmetic Act (FFDCA). Until rapid tests are developed, it is difficult for FDA's import monitoring system to identify problem microbial pathogens in food imports quickly. Congress is considering whether testing technologies and the monitoring of imported foods for microbial pathogens are adequately ensuring that safe food is imported. It does not appear that more sampling at the border will adequately address hazards in imported foods. Congress is monitoring USDA's and FDA's implementation of a new approach, called Hazard Analysis and Critical Control Point (HACCP), to meat, poultry, and seafood safety. It is also considering bills that would impose country of origin labeling on some food imports and reorganize federal agencies into a single food safety agency.

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The Safety of Imported Foods: The Federal Role and Issues Before Congress

Introduction

The increasing globalization of the U.S. food supply has brought a variety of nutritious food choices to America's diet while posing challenges to the federal government to ensure that all these foods are safe.[1] Dr. Michael Friedman, Lead Deputy Commissioner of the Food and Drug Administration (FDA), has stated that, while FDA believes that imported foods are generally safe, recent outbreaks of foodborne illnesses demonstrate that imported foods can introduce new risks and the increased consumption of imported foods heightens those risks.[2]

It is unclear if imported foods are less safe than domestically produced foods. Economists at the Economic Research Service (ERS) of the U.S. Department of Agriculture (USDA) concluded that there is no clear evidence of differences in the safety of imported and domestically produced products.[3] Pathogens associated with all food, including imported foods, however, have caused concern among public health officials. The General Accounting Office (GAO) reported in April 1998 that at least 16 outbreaks of foodborne illnesses have been linked to imported foods since 1988 based on data from the Centers for Disease Control and Prevention (CDC).[4]

Foodborne illness is a public health problem whether or not it is linked to imported food. According to experts, each year in the United States an estimated 6.5 million to 33 million people get sick and 9,000 die from illnesses caused by foodborne pathogens. Although these estimates are under debate,[5] most of those known to be affected are the very young, the elderly, and the immuno-compromised.

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[1]F.K. Kaferstein, Y. Motarjemi, and D.W. Bettcher, "Foodborne Disease Control: A Transnational Challenge," *Emerging Infectious Diseases*, vol. 3, no. 4, October-December 1997, 503.

[2]Statement from Dr. Michael Friedman, Lead Deputy Commissioner of the FDA, in GAO Food Safety Report, May 11, 1998. General Accounting Office, *Food Safety: Federal Efforts To Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103, April 1998.

[3]Glenn Zepp, Fred Kuchler, and Gary Lucier, *Food Safety and Fresh Fruits and Vegetables: Is There a Difference Between Imported and Domestically Produced Products?*, Vegetables and Specialties/VGS-274/April 1998, ERS, USDA, 23-28.

[4]General Accounting Office, *Food Safety: Federal Efforts To Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103, April 1998.

[5]Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Ames, IA, 1994. Also see Dan Wilson, "Food Poisonings' Phony Figure" *CJR*, May/June 1998, 16.

In just one month, June 1998, over 5,000 cases of illness caused by foodborne pathogens in 41 states were reported to CDC.

The increasing volume of food imports inspected at U.S. ports of entry is stretching federal resources. For example, in fiscal year (FY) 1985, FDA recorded under a million food shipments being presented at U.S. ports of entry, while in FY1998, the agency recorded more than 3 million shipments. Most imports are perishable foods.[6] FDA's inspection data for FY1997 show that vegetables, seafood, miscellaneous foods, alcoholic beverages, and fruits were the most numerous imports.[7] (See Appendix A, Table A-1.) As food imports increased, FDA has been able to physically inspect fewer shipments than previously — in FY1992, FDA examined 8% of all food entries under its jurisdiction; by 1997 it only examined 1.7%. (See Appendix A, Table A-2.)

Under the current import inspection system, many pathogens and chemical contaminants that could pose risks to public health are more virulent and hard to detect.[8] For example, most of the 2,477 U.S. cases of cyclosporiasis during 1996 and 1997 were associated with raspberries imported from Guatemala but FDA could not have detected the *Cyclospora* protozoa parasite in the raspberries at U.S. ports of entry without destroying the raspberries. Inspection methods that rely on physical inspection of marketed shipments or sampling cannot detect many types of microbial pathogens in foods. Some pathogens need special laboratory tests to be detected.

In light of these concerns, some Members of Congress, the GAO, food safety experts, and a number of U.S. consumers have begun questioning whether the current food safety system for imports, based on government inspections at the border, is sufficient to protect U.S. consumers. Questions have been raised about whether the current federal agencies with food safety responsibilities for imported foods have sufficient resources to do their job. Some question whether these agencies need more legislative authority to go overseas to inspect other countries' food safety systems; still others question whether the responsible U.S. federal agencies are using their current authority in the most productive manner.

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[6] U.S. Department of Agriculture. Outlook for U.S. Agricultural Exports. Approved by the World Agricultural Outlook Board, Economic Research Service, and Foreign Agricultural Service, AES-12, December 4, 1996 and ES-16, December 2, 1997.

[7] Food and Drug Administration, OASIS System, July 1998.

[8] Since 1973, 29 new pathogenic microbes (bacteria, viruses, and parasites) and infectious diseases have been recognized. Many of these have been associated with foodborne illness outbreaks. Microbial pathogens causing these illnesses vary. For example, *E. coli* O157:H7 has been found in meat, cole slaw, and apple juice, *Salmonella* in eggs, vegetables, ice cream and cereal, *Cyclospora* on raspberries and basil, *Crytosporidium* in drinking water, *Hepatitis A* virus in frozen strawberries, and *Campylobacter* in poultry. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after becoming more virulent and resistant to antibiotics. Joshua Lederberg, "Infectious Disease as an Evolutionary Paradigm," *Emerging Infectious Diseases*, vol. 3, no. 4, October-December 1997, 419.

This report describes the food safety import inspection systems of both FDA and USDA and characterizes Administration efforts to set requirements for cooperation among these agencies. The remainder of the report discusses issues of funding and policy mechanisms that are under congressional debate.

Food Safety Responsibilities of Federal Agencies

Five cabinet departments with fifteen federal agencies have jurisdictional responsibilities dictated by federal law for the safety of imported foods.[9] Two agencies, FDA and USDA, hold most of the responsibility for covering the entire food chain from farm to table. Their jurisdictions over imported food depend on the type of food being imported. USDA's Food Safety Inspection Service (FSIS) regulates red meat,[10] poultry, and shell eggs. FDA is responsible for the safety of all other foods, including seafood. Within FDA, two centers have food safety programs — the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). The National Center for Toxicological Research (NCTR) supports the regulatory activities including research of all FDA centers. (FDA is within the Department of Health and Human Services (DHHS)). The Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) regulates pesticide residues in or on all foods, including imports. In addition, the Centers for Disease Control and Prevention (CDC), also a part of DHHS, tracks foodborne illness incidents and outbreaks, domestically and worldwide, and provides data and information to the other food safety agencies. The National Marine Fisheries Service of the Department of Commerce conducts a voluntary seafood inspection and grading program which is used mainly by seafood exporters.

Federal laws mandate how the two major federal agencies carry out their roles in food safety, and these laws dictate very different approaches. To be allowed entry, imported foods must comply with the same U.S. safety standards as required for domestically produced foods. These standards require that the food must be wholesome, safe to eat, produced under sanitary conditions, and properly labeled. These standards allow federal agencies to refuse entry of imported food that appears to be adulterated or misbranded. The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes FDA to react to problem foods, either domestic or imported. FDA's responsibility is to determine whether the food presented at U.S. ports of entry is safe and truthfully labeled. FSIS implements the Federal Meat Inspection Act that mandates that meat imported into the United States equal U.S. standards for safety. Congress instituted similar requirements for poultry in the Poultry Products Inspection Act. Imported foods that contain any pesticide residues must meet the

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[9]Other agencies within USDA hold some food safety regulatory responsibilities: Agricultural Research Service, Cooperative State Research, Education, and Extension Service, Economic Research Service, National Agricultural Statistics Service, Office of Risk Assessment and Cost-Benefit Analysis. Also the Bureau of Alcohol, Tobacco, and Firearms and the U.S. Customs Service have certain responsibilities. The National Institutes of Health supports research related to food safety problems as they affect human health. Currently, discussions are underway to consolidate the seafood activities of the National Marine Fisheries Service (NMFS) with FDA's Office of Seafood.

[10]FDA has jurisdiction over game meat.

tolerance regulations established by EPA under Section 408 of the FFDCA. EPA has set over 9,000 pesticide residue tolerances or legal limits on the amount of residue that can be found in or on particular foods. FDA and USDA enforce those tolerances on the food supply.

Federal laws mandate safety standards and federal agency personnel inspect products to ensure compliance with these standards. In theory, U.S. domestically produced foods are monitored in the production, processing, and shipping stages to ensure their safety. They are then inspected and sampled occasionally to test for specific risks. But most imported foods, other than meat and poultry, are not monitored and inspected until they reach the border. So this oversight of imported food, other than meat and poultry, can not be as extensive as that conducted for domestically produced foods.[11]

Food and Drug Administration's Inspection System

An importer, or his/her agent, files entry documents with the U.S. Customs Service (Customs) within five working days of the date that a food shipment arrives at a U.S. port of entry. (The importer posts a bond with Customs to cover potential duties, taxes, and penalties.) Customs notifies FDA of the shipment by forwarding copies of Customs documents, commercial invoices, or bond guarantees. FDA inspectors review electronic or paper copies of all entry documents with a computerized system, the Operational and Administrative System for Import Support (OASIS). This system automatically screens all these documents. The FDA inspector then decides whether to conduct a physical examination, wharf examination, or take a sample from the shipment for analysis.

If the FDA inspector decides not to examine or sample the shipment, he/she releases the shipment by sending a "may proceed notice" to the importer and Customs, usually electronically. If the FDA inspector decides to examine or sample the shipment, the importer and Customs are notified and the importer must hold the shipment intact pending further notice, although the shipment may be moved from the dock to another port or warehouse. The computerized screening system OASIS uses a variety of risk-based criteria to target food shipments for further inspection. The criteria include that: the importer has a prior history of violations; there have been problems with the same product from a particular country, manufacturer, or shipper; a large volume of the product is being imported and is important in the American diet; and other factors. Samples may be taken from food items such as soft cheeses that have a high potential for microbiological contamination, or risk, or from low acid canned foods, etc. The screening criteria always include a default examination rate so any product could trigger an extensive review. This default system ensures that every product offered for import has some possibility of being examined.

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[11]Committee to Ensure Safe Food from Production to Consumption, *Ensuring Safe Food From Production to Consumption*,(Washington, D.C.: National Academy Press), 20 August 1998, 47.

In FY 1997, FDA's OASIS system recorded and reviewed 2,765,548 line entries (shipments) of food products.[12] Of these entries, FDA allowed 55% to go into U.S. commerce without additional FDA scrutiny; the other 45% were reviewed by FDA. (See Appendix A, Table A-1.) Many imported foods are value-added foods that are cooked and/or ready to eat. FDA officials have found that currently 38% of fruits, 12% of vegetables, and 55% of seafood consumed in the United States are imported. These percentages may increase as imports increase.

Generally, FDA defines food entries as any shipment that contains food products from one manufacturer, shipper, grower, importer or country or that has the same manufacturer code and/or the same label. These food line entries can be raw agricultural commodities, produce, or processed foods. For example, a shipment of food, such as cucumbers from a Mexican cooperative, would be defined as a single food entry. Each entry must have its own set of papers which identifies the shipment as containing food products from one manufacturer/shipper/importer/grower/country.[13] FDA may examine a food entry regardless of the value of the shipment if there is concern that the food may pose a hazard to public health. Generally, however, FDA does not sample food shipments having a value less than $200.00.

If FDA obtains a physical sample of the shipment, it is sent to an FDA district laboratory for analysis.[14] If it is in compliance with FDA's requirements of being safe, wholesome, and properly labeled, FDA sends the importer and Customs a "release notice." The shipment may then proceed into commerce.

If FDA finds a shipment in violation of the safety requirements, it will mark the documentation "refusal of admission" and send the importer and Customs a "notice of detention and hearing." The notice will specify the violation and give the importer 10 working days to show why the shipment should be admitted. At the hearing the

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[12]This number does not include a substantial number of informal food entries, valued at $2,000 or less, that are not processed through OASIS, *Federal Register*, vol. 63, No. 64. 3 April 1998, 16414-16417.

[13]There is a different line entry for different products, manufacturers, or package size.

[14]FDA collects samples for two purposes: surveillance and compliance. The name fits the motivation or reason behind the sampling. Surveillance samples are collected in the course of routine monitoring of imports, even if FDA inspectors do not suspect any specific violation. Compliance samples are taken where prior violations have occurred, where FDA suspects that "good manufacturing practices" have not been followed, or if the imported product has been highlighted for coverage under a special assignment, e.g., lead in dinnerware. Sampling identifies many hazards, usually in time to stop distribution and minimize public exposure. For example, low-acid canned food import paperwork is examined to see if the product manufacturer has registered with FDA. Also, FDA inspectors may visually examine canned food entries and, if they notice obvious indications of problems such as swollen, rusted or leaking cans, they can stop the shipment. Observed defects can also result in samples being collected and tested for pathogens and may identify problems that can have serious health consequences. Where possible, perishable fresh fruits and vegetables are given priority handling with samples collected and analyzed within 24 to 36 hours. However, testing for *Salmonella* in fresh fish requires 15 days, so the product is frozen. FDA pays importers for all samples it takes if the samples are found to be in "compliance."

importer is given the opportunity to present evidence of compliance or a plan of how the product could be brought into compliance with safety requirements and be admitted into the United States. If no evidence is presented that satisfies FDA, the agency issues a "notice of refusal of admission" to the importer and Customs. Customs ensures that the refused shipment is re-exported or destroyed within 90 days.

At the FDA hearing, the importer can choose to present evidence from a laboratory of its choice showing that the shipment samples comply with published guidelines for contaminant levels and defects in food. Or the importer can apply for permission to recondition the shipment or suggest some other remedy to address the problem. Proposals for reconditioning could mean fumigating, sifting and cleaning bulk grains to eliminate the filth, re-labeling, cooking, repackaging, or converting the food shipment to a non-food use, etc. The FDA has the discretion to accept or reject reconditioning proposals. FDA often collects follow up samples to determine if the shipment complies with its requirements.

FDA defines an "examination" as being as simple as an inspector walking by the shipment or a field exam where an inspector inspects by physically handling the food entry. It also means that samples can be collected in the course of routine monitoring of imports. The inspector could either take a sample and have it analyzed[15]or the inspector could automatically detain a lot without physical examination because the agency suspects that the import may contain a public health hazard. If the product, shipper, or exporting country has a history of violations, the FDA may place all shipments in a category called "detention without physical examination (DWPE)." This category was known as "automatic detention." The products are detained until FDA receives evidence that suspected food shipments, tested by private laboratories, are shown to be admissible. (See Appendix A.)

FDA has never had the resources to inspect all food shipments coming into the United States. Rather, importers, manufacturers, producers, and distributors of food, here and abroad, have the primary responsibility for meeting U.S. standards and for ensuring that food, when marketed in interstate commerce, is not harmful or unfit and does not contain unacceptable chemical residues. FDA periodically inspects whether food manufacturers are adhering to their legal responsibility of ensuring that foods are not found to be defective, unsafe, filthy, or produced under unsanitary conditions.

Since 1992, the number of import examinations has declined as have the number of FDA import food inspectors. Table 1 shows the number of full time equivalent positions allocated to inspect imported foods over the last 11 years. The average number of positions remained constant at about 40% of FDA's work force involved with food, while the number of shipments increased substantially. FDA contracts with individual states to conduct FDA inspections of some imported foods to ensure they meet federal and state requirements.

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[15]The analytical methodology used for finding microbial pathogens is organism specific. The methodology used to detect *Salmonella*, for example, will not detect the parasite *Cyclospora*.

Table 1. FDA's Field Full Time Equivalent (FTE) Positions Allocated to Imported Foods, FY 1986 to FY 1997

Fiscal Year	FTEs in Field Offices Involved with Imported Foods	Total FTEs in Field Offices Involved with Food	% FTEs Involved with Imported Food
1986	389	1138	34
1987	387	1105	35
1988	470	1181	40
1989	509	1281	40
1990	544	1327	41
1991[a]	577	1488	39
1992	591	1524	39
1993	583	1491	38
1994	614	1517	40
1995[b]	645	1480	44
1996	595	1452	41
1997	556	1406	40

[a]In FY 1991, an additional 86 FTEs were appropriated for the Office of Seafood (35 for imported seafood and 51 for domestic seafood). However, Congress did not appropriate funds to cover their salaries.
[b]From FY 1995 onwards, resources for imported food inspections have declined.

Source: Food And Drug Administration, Office of Legislative Affairs, Memorandum from Lois Adams, June 16, 1998.

U.S. Department of Agriculture's Inspection System

USDA's FSIS shares similar enforcement objectives with FDA: to ensure that safe and wholesome foods (meat and poultry) are accurately labeled whether they are produced domestically or overseas. Its inspection system, however, is very different from FDA's because FSIS requires that countries exporting meat, poultry, and egg products to the United States have an inspection system which certifies that exported meats will, at a minimum, equal U.S. standards for safety. To ensure such standards, FSIS officials comprehensively review an exporting country's laws, policies, and regulations. In addition, FSIS officials conduct different levels of inspections ranging from meetings with officials to on-site visits to foreign processing plants to

determine how well the country implements HACCP,[16] and controls disease, residues, contamination, and economic fraud.

Imported meat accounts for about 7% of domestic consumption; imported poultry and egg products account for less than 1% of U.S. domestic consumption. Over 85% of these imports are further processed under FSIS supervision.

The foreign government of a country that wants to export food to the United States must maintain an inspection system and personnel that are capable of overseeing that all U.S. meat and poultry import requirements are met. In 1996, 6,148 foreign government inspectors were licensed to conduct ante-mortem and post-mortem veterinary inspections of all animals at the time of slaughter. They approve sampling and analytical methods for testing tissues for specific compounds, test meat for potential contaminants, check slaughter plants daily for sanitation, and certify that the product has met all U.S. requirements.[17]

As part of a foreign government's inspection system, meat processing plants must send processed products on a regular basis to laboratories to monitor for chemical residues and microbial contamination. Foreign governments certify which processing plants meet all U.S. requirements. Foreign inspectors sign certificates accompanying each food shipment containing meat to ensure that the meat is labeled with the country and plant of origin, the volume, and the shipping marks.

FSIS reviewers return to exporting countries on a regular basis to determine whether the country's policies, programs, and meat plants continue to meet U.S. requirements. As of September 24, 1998, approximately 37 countries were authorized to export to the United States. Canada, Australia, New Zealand and Denmark are by far the largest suppliers of meat imports into the United States.

The system for meat and poultry imports at the border is known as USDA's "reinspection program" and is, in a sense, the second layer of protection for it serves as a check on the effectiveness of the foreign certification program. A description of each meat lot arriving at U.S. ports is entered into the FSIS's Automated Import Information System (AIIS). FSIS's reinspection sampling is based on a combination of random sampling, on prior experience with a country or company, or if FSIS inspectors suspect a problem. In 1997, 75 FSIS import inspection personnel

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[16]FSIS has mandated that the Hazard Analysis and Critical Control Point system (HACCP) be used by all domestic and imported slaughter and processing operations. The HACCP approach to food safety requires that the processor has put into place some control mechanisms at points in the food production system where it believes a hazardous and/or a critical situation could result in an unacceptable health risk or regulatory violation. Such a system's approach covers risks or violations related to contamination from pathogenic microorganisms, chemical residues, adulteration, and misbranding. Under HACCP, the processor must check any point in the process, storage, or distribution system where there is risk of a hazard entering the food. Imported meats and poultry products must meet HACCP standards of inspection.

[17]9 CFR 327.4 for inspection certificates for meat and meat product imports; 9 CFR 381.197 for poultry imports inspection certificates.

reinspected meats at 156 official import establishments.[18] In 1997, FDA reviewed 118,000 shipments and conducted laboratory tests on about 20 percent of these shipments.

Presidential Food Safety Initiatives

The President has initiated several interagency efforts to improve the current system of ensuring that imported foods are safe in the last 2 years.

President's Food Safety Initiative

In 1997, the President launched a Food Safety Initiative to improve methods to track and prevent foodborne illness. An interagency effort produced a report entitled, *Food Safety from Farm to Table: A National Food Safety Initiative* that addressed a number of problem areas, including problems with imported foods. For example, it called upon the federal agencies with food safety responsibilities to: ensure that both domestic and imported food is safe, identify hazards that present the greatest risk to public health, make the best use of public and private resources, increase collaboration between the federal government and industry and consumer groups, and improve coordination within the federal government and between federal, state, and local governments. It also identified problems that arise because different regulatory agencies have different approaches to imported foods.

Produce Safety Initiative

Because of the increasing concerns about risks from imported fresh fruits and vegetables, the President announced in October 1997 a series of activities to cope with questions about the apparent increased risk of foodborne pathogens that could potentially be found in imported produce. This initiative required FDA to issue guidance on good practices for fruits and vegetables, to work towards gaining agreements with trading partners to ensure that their standards are equivalent with those of the United States, to issue rules requiring a warning label be placed on unpasteurized fresh juices, and to promulgate final rules for processing all fresh juices. Most of the activities so far have targeted domestically grown produce. Imports, however, will have to meet these same criteria.

FDA will soon be issuing the final guide on good agricultural practices for U.S. produce growers. The guide will discuss microbiological quality of irrigation water and the use of untreated animal waste as fertilizer. Industry officials have expressed concern that produce wholesalers/buyers may insist these standards are followed before they purchase produce. Such insistence could have the effect of making the guidance more like mandatory standards and disrupt trade, they argue.

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[18]U.S. Department of Agriculture, Food Safety and Inspection Service, "1996 Report of the Secretary of Agriculture to the U.S. Congress," September 1997, 41-45. Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, Hearing on Improving the Safety of Food Imports, Statement of Thomas J. Billy, Administrator, Food Safety and Inspection Service, USDA, 105th Cong., 2nd sess., September 24, 1998.

The President's Council on Food Safety

On August 25, 1998, President Clinton signed an executive order establishing the President's Council on Food Safety. The Council will be headed by the Secretaries of Agriculture and Health and Human Services and the Assistant to the President for Science and Technology. As announced, its published purpose is to develop a plan that contains recommendations on changes needed to reach food safety goals, to coordinate the annual food safety budgets of all the federal agencies, to assist in developing priorities for food safety research, and to report back to the President within 180 days with its views on the National Academy of Sciences (NAS) report entitled *Ensuring Safe Food from Production to Consumption.*[19] This report recommends that the federal government adopt a science-based approach to food safety that would prevent, identify, and target the largest threats to the food system and change federal statutes so that inspection, research, and enforcement are rooted in scientifically supportable assessments of risk to public health. It also recommends ways to enhance coordination among federal food safety agencies by establishing a unified, central framework for managing food safety programs headed by one official with control of resources for all federal food safety activities.

Issues Facing Congress Regarding Imported Foods

Funding

Funding for imported food inspection systems are included in both FDA's and FSIS's total budgets. Since FY 1993, FSIS's resources allocated to import inspections have remained relatively constant while FDA's resources allocated to import inspections have risen. (See Table 2.)

Appropriations. In FY1998 appropriations, Congress allocated $205 million to pay for the President's Food Safety Initiative. For FY 1999, Congress refused a request for $109 million in additional funds. Rather, Congress appropriated $257 million with an additional $51.9 million. FDA will receive $20 million; the USDA $27.2 million; and the allocation of the remaining funds is unclear.

User Fees. To increase resources for food inspections, FDA and FSIS have asked Congress to authorize the collection of general user fees. The federal government defines the term "user fee" as any fees, charges, or assessments levied on the private sector directly benefitting from a government program.[20] The Imported

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[19]Committee to Ensure Safe Food from Production to Consumption, *Ensuring Safe Food From Production to Consumption*,(Washington, D.C.: National Academy Press), 20 August 1998, 90.

[20]Congressional Research Service, *Federal User Fees: An Overview*, by Julius W. Allen, CRS Report 89-625 E, 31, October 1989. Also see U.S. President's Council on Integrity and Efficiency, *Audit of the Establishment and Collection of User Charges*, Washington, 1989, 7.

Table 2. Funding Allocated to FSIS and FDA Import Inspections
Fiscal Years (FY) 1993 - 1997, with an Estimate for FY 1998.
(Millions of Dollars)

Fiscal Years	USDA's Food Safety and Inspection Service	Food and Drug Administration[1]
1993	10.9	33.6
1994	11.3	38.6
1995	11.2	40.2
1996	10.2	41.4
1997	10.2	41.5
1998 est.	10.5	42.8

[1]FDA's funding covers only the field import program and does not include administration or funding for work of the Center for Food Safety and Applied Nutrition (CFSAN).
Source: FSIS funding provided by Chris Zehren, USDA Budget Office; FDA's funding was provided by Lisa Siegel, FDA Budget Office.

Food Safety Act of 1998 (H.R. 4080 introduced by Representative Dingell) contains a proposal to authorize FDA to charge $20 or less per imported food line entry. The fee would not be based on the value of a shipment of imported food. The proposed $20 fee would be based on the cost of processing and approving food imports and would include the cost of sampling and testing. The total revenue collected from fees would be used for two purposes: half would be used to fund an increased number of port-of-entry food inspectors; and the second half would be spent on research to develop rapid testing methodologies to detect pathogenic contamination. The proposal is that the collected revenue be in addition to, but not replace, appropriated funds and be adjusted for inflation and other factors. The proposal would authorize $56 million each year from FY 1999 through FY 2003.

The Administration supports the idea of "general user fees" and has asked for them in budget requests. Two consumer groups also support the idea of charging importers a modest fee to improve border inspections.[21] Critics of this specific proposal for user fees view it as a new regressive federal food tax that would be passed on to U.S. consumers through higher food prices. Some in the industry are concerned that other countries could view this user fee as a nontariff trade barrier and would retaliate against U.S. food exports. In addition, some argue that the assurance of safe food is a fundamental government function and should not be passed on to importers or consumers. One consumer advocate stated that rather than user fees on import line item entries, FDA should require that both domestic and foreign food

[21]Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, Hearing on Federal Efforts to Ensure the Safety of Food Imports, Statement of Carol Tucker Foreman, on behalf of the Recife for Safe Food Campaign, a joint project of the Safe Food Coalition and the Center for Science in the Public Interest, 105th Cong., 2nd sess., 24 September 1998, 6.

companies register with FDA for a nominal registration fee. This would give the agency revenue and the name and address of every food processor and importer that the agency has an obligation to inspect.[22] This information could facilitate any agency action on tracing back products that would be associated with foodborne illness outbreaks.

Mechanisms for Ensuring the Safety of Imports

Border inspections capture some problems with imported foods at U.S. ports of entry, but not all. Recent foodborne illness outbreaks caused by pathogens associated with imported raspberries and strawberries raised questions about the system that ensures the safety of imported foods. Some question whether border inspections are enough to control the risk of hazards and whether increased numbers of inspectors and sampling of import shipments would necessarily increase the safety of imported foods. Checking samples can only test for specific known risks on a given day. Border officials may not know where the most significant risks are. GAO has argued that because FDA inspectors cannot readily obtain health risk data that would help them choose the shipments likely to pose health risks, some shipments that cause health problems make it into U.S. commerce.[23] FDA's inspectors may take samples from import shipments, but the laboratory staff told GAO that they were overloaded with work and sometimes could not conduct the tests that could detect filth and microbial pathogens in imported foods.

Others argue that because border inspections are not fully effective against current hazards and microbial pathogens, FDA inspectors should go overseas to attempt to grade food safety systems and sanitation in countries that export foods to the United States. They want Congress to authorize FDA to negotiate "equivalency" agreements — the legal authority to require that imported products be produced under sanitary, manufacturing, packing conditions equivalent to those in the United States — with other countries to ensure that the source of hazards in foods is stopped. Others insist, however, that the current statute gives FDA the authority to negotiate equivalency agreements and that augmenting resources for the current inspection system would improve the safety of imported foods. In addition, several industry groups argue that U.S. importers are very aware of production problems overseas and that private industry is working with other countries to mitigate many problems.

More Equivalency Arrangements. According to the April 1998 GAO report, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable,* federal agencies are not doing a good job of managing problems with

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[22]Caroline Smith-DeWaal, Center for Science in the Public Interest, as quoted in "Food Safety, Dingell, Commerce Democrats Introduce Bill Seeking More FDA Import Checks," *Daily Report for Executives*, No. 117, Washington, D.C. : Bureau of National Affairs, Inc., 18 June 1998.

[23]General Accounting Office, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103, April 1998, 29.

imported foods.[24] GAO concluded that border inspections alone were ineffective and that FDA cannot realistically ensure that unsafe, adulterated, or misbranded foods are kept out of the United States through such inspections. GAO concludes that FDA lacks the authority that FSIS has to mandate "equivalency." GAO said that FDA should be given this statutory authority along with resources to inspect systems overseas to certify that they are equivalent to U.S. levels of protection.[25]

FDA agrees with GAO that it needs such "equivalency" authority in order to ensure more fully the safety of imported foods. FDA has the authority under the implementing legislation of the Uruguay Round Trade Agreements to enter into equivalency agreements with other countries. But FDA does not require nor does it want to require such agreements before trade can occur.[26] FDA supports enactment of the Safety of Imported Food Act of 1998 (S. 1707, introduced by Senator Mikulski, and H.R. 3052, introduced by Representative Eshoo), which would amend the FFDCA, and authorize FDA to go to other countries to ensure that all FDA-regulated foods, including produce, imported into the United States are being prepared, packed, or held under conditions that ensure safety. S. 1707/H.R. 3052 would allow the agency to halt food imports from countries that refuse to allow U.S. inspections of their food facilities or systems. The bills do not mandate that a foreign country have a food safety system "equivalent" to that of the United States. They do not require that FDA evaluate a foreign country's food safety system as a precondition to admitting food imported from that country. Rather they require that the foreign system achieve the same level of protection or safety that domestically produced U.S. products must meet.[27]

Authority proposed in S. 1707/H.R. 3052 for FDA could be used in negotiating with U.S. trading partners over import access. Supporters of this measure think that overseas inspections are vital to ensuring imported food safety and emphasize a country's food safety control system at the source. Overseas inspections would take into account the production, processing, and handling of food products rather than relying exclusively on border inspections. Supporters argue that with equivalency

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[24]*Food Safety: Federal Efforts to Ensure Imported Food Safety Are Inconsistent and Unreliable*, Statement of Robert E. Robertson, Associate Director, Food and Agriculture Issues, Resources, Community, and Economic Development Division, General Accounting Office before the Permanent Subcommittee on Investigations, Senate Committee on Governmental Affairs, 14 May 1998.

[25]The "level of protection" of a country is the system for limiting risk that a society requires relative to a particular hazard. The limitation of risks depends upon adequate production and manufacturing controls for food in the country of origin.

[26]General Accounting Office, GAO/RCED-98-103, April 1998, 53.

[27]The idea of "equivalency" does not necessarily mean identical measures but rather includes any measure that protects human health from risks in food or from a country's "level of protection." (See footnote 25) Measures are applied that achieve the importing member country's level of sanitary or phytosanitary protection. These measures may be laws, decrees, and regulations and procedures relating to end-product criteria and processes and production methods, testing, and inspection as stated in the Sanitary and Phytosanitary Agreement (SPS agreement). The burden of demonstrating equivalence would rest with the exporting country.

agreements in place, the cost to FDA for inspections and surveillance would be much less. Critics claim that inspections will not necessarily make imported food safer. They argue that FDA's inspections of food processing facilities in other countries would be limited because they would be extremely costly.[28] They state that for very specific products, such as infant formula producers or low-acid canned food manufacturers, FDA already inspects production facilities consistently but because there are few producers of these products, inspections are not numerous.

Two other bills would require that FDA negotiate equivalency agreements to ensure that the exporting nation has an adequate system for preventing problems in foods exported to the United States. The Consumer Food Safety Act of 1998 (H.R. 3676, introduced by Representative Pallone) would require that all processors and importers be inspected quarterly to prevent food imports that would not meet the safety standards of the FFDCA. It also would mandate FDA to certify under bilateral agreements that food products must be produced under a specific program which ensures their safety. The Imported Food Safety Act of 1998 (H.R. 4080, introduced by Representative Dingell) would require FDA to consider, before releasing food at the port of entry, whether the importers were cooperative, have a history of compliance failure, whether the food or the country from which it came has a history of problems, whether the foreign country provides the same level of protection as the United States, and whether the foreign country permits inspections.

Such monitoring of trading partner food systems, as worded in all the bills could, according to FDA, prevent potential health problems if the agency could also look at produce-growing conditions and food handling practices to ensure that the food to be exported to the United States would be safe. Such an examination of foreign government food safety systems would allow FDA to gain more knowledge of potential pathogens that could exist in the imported food and make sample testing more focused. FDA supports the idea of "equivalency" agreements but claims that standards of equivalency should not be mandated but should be applied when FDA believes it is most appropriate, thus limiting disruptions in trade.

Equivalency agreements may not be reached easily with some trading partners. One U.S. delegation found it difficult to explain U.S. regulations on drugs and food additives to their foreign counterparts[29] because U.S. regulations on these substances are scattered throughout the *Code of Federal Regulations* and are sometimes difficult to understand. In addition, in this instance, all the personnel negotiating the agreement for the trading partner had been completely replaced by the end of the process. Some items needed to be renegotiated.

Congress may consider whether or not to encourage and authorize international bilateral "equivalency" arrangements and/or urge the Administration to take a stronger leadership role in international standard setting organization activities (See Appendix B.) FDA currently has 29 bilateral food-related agreements with trading

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[28]Allen Freedman, "Unsafe Food Sparks Outbreaks of Concern, Little Action," *CQ Weekly*, 30 May 1998, 1436-1440.

[29]Mary Snyder, Food and Drug Administration, conversation with author, September 23, 1998.

partners to exchange information and expertise, to mutually recognize inspection reports and products to eliminate duplication of activities, and to achieve international harmonization. Critics in the U.S. food industry are very concerned that requiring equivalency agreements would violate international trade agreements and mandating that all imported food come under equivalency agreements would disrupt the flow of foods into this country.

USDA Enforcement Activities. When meat is imported into the United States, it comes under the control of USDA and its FSIS before being released into commerce. If the shipment is refused entry, the boxes are marked as such and must be reconditioned, re-exported, or destroyed within 45 days.

Critics question aspects of this import regulatory system. Many have criticized FSIS for emphasizing problems such as incorrect labeling in its inspections as opposed to emphasizing more serious public health risks. The April 1998 GAO report stated that FSIS targets shipments for more intensive inspections based on whether a foreign firm has a history of violative behavior. GAO listed violations such as missing shipping labels, incorrect weight, or misidentified products as examples of violations that do not pose a direct health risk to consumers. These violations trigger FSIS inspections of every shipment from a foreign firm until the firm reestablished a good track record with 10 consecutive shipments in compliance with U.S. regulations. In 1996, about 86% of refused shipments by FSIS (excluding those refused for transportation damage) were not directly related to health risks. FSIS used resources on these shipments rather than using more resources on products that could cause greater health risks, according to GAO.[30]

FSIS, however, disagrees. In the same report, the agency refutes GAO's finding and claims that in 1996, 80% of the violations on imported meats were the result of health risk problems. FSIS officials argue that these problems were found through laboratory analysis which showed excessive residues and microbiological contamination. Also FSIS inspectors found unwholesome products through physical inspections.

FDA Enforcement Activities. GAO found that FDA lacks the necessary controls over detained and suspect shipments. FDA's inspection system allows importers to retain custody over shipments throughout the import process. If a shipment is found to violate U.S. standards (called a violative shipment), importers are allowed 90 days to re-export or deliver refused shipments to Customs for disposal. Customs, responsible for the violative foods being re-exported or destroyed, can penalize importers for not completing this task. Customs can collect penalties up to 3 times the invoice value of the refused merchandise. But some importers are not greatly concerned about having to pay this penalty and consider the cost of the penalty to be part of their cost of doing business. According to GAO and other critics, penalties need to be greater to deter infractions.

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[30]General Accounting Office, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103, April 1998, 28.

GAO claims that FDA's inspection system is vulnerable to unscrupulous importers for several reasons. Importers may:

- falsify laboratory test results on suspect foods to obtain a release from FDA of their products;
- sell potentially unsafe imported foods before FDA can inspect them; or
- sell imported foods that FDA found violative and barred from entry.[31]

In a series of hearings by the Senate Committee on Government Affairs, Permanent Subcommittee on Investigations, witnesses testified that weaknesses in FDA's controls over food imports enable the entry of unsafe food products into U.S. commerce. Congress was told that some importers are unscrupulous and fraudulently substituted shipments, filed false documents, and/or mislabeled products. Witnesses explained that the inspection system failed in part due to miscommunication between the regulatory agencies and Customs.[32]

In response to this criticism, FDA stated that it tries to anticipate risks and problems associated with products and countries exporting to the United States. In doing its job, FDA's import system focuses on hazards, such as heavy metals, pesticides, chemical contaminants, natural toxins, allergens, known pathogens, histamines in seafood as well as emerging pathogens. An FDA official stated at the September 24, 1998 hearing held by the same Subcommittee that the agency is currently considering improving its control over food shipments by marking refused goods "refused" and improving communications with the U.S. Customs Service.[33] FDA lacks the authority to require importers to use certain laboratories from a list of accredited laboratories. However, FDA has issued new instructions to its district offices regarding the use of independent laboratories.

Customs wants authority to increase monetary penalties from the current limit of up to 3 times the market value when refused products are not exported or destroyed. Customs also stated at the Subcommittee hearing that it would like to use FDA's "notice of refusal" as its notice of delivery. By doing so, Customs would learn immediately which shipments were refused by FDA. Customs officials suggested that Customs require a separate bond for each shipment entered by the high risk importers. At the hearing, a Customs official testified that in a special enforcement operation, Customs found that food imports from six countries comprised 40% of the detected violations of shipments.[34] One food industry spokesman supported the idea

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[31]General Accounting Office, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103, April 1998, 42-43.

[32]Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, The Safety of Food Imports 105th Cong., 2nd sess., 14 May, 9 July, 10 September 1998.

[33]Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, Hearing on Improving the Safety of Food Imports, Statement by William B. Schultz, Deputy Commissioner for Policy, FDA, DHHS, 105th Cong., 2nd sess., 24 September 1998.

[34]Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, (continued...)

of punishing repeat violators by calling on FDA, rather than Customs, to target importers with multiple safety-related violations for frequent and rigorous inspections and greater sanctions.[35]

Several bills introduced in the 105th Congress would strengthen FDA's regulatory authority over imported food. The Consumer Food Safety Act of 1998 (H.R. 3676) would establish procedures by which consumers would notify FDA of adulterated foods, including imported foods. It would strengthen FDA's authority for seeking recalls, and in levying civil money penalties. If importers failed to comply with FDA's order to dispose of food, the Imported Food Safety Act (H.R. 4080) proposes that they would be found in violation of the FFDCA, and could incur criminal penalties. GAO has suggested that Congress may want to give FDA authority to have available a full range of penalties to establish appropriate deterrents to penalize importers and prevent infractions.

FDA Import Monitoring and Detection Methodologies. Without more resources to monitor imports and to develop technology to detect and track emerging infectious agents and pesticide residues in foods, it will continue to be difficult for FDA's system to identify problem pathogens quickly in perishable foods and to take decisive action to prevent violative foods from entering U.S. commerce. FDA has successfully monitored pesticide residues in imported foods but lacks rapid detection methods and risk assessments for many foodborne pathogens.

Pesticide Residue Monitoring. FDA officials claim that their testing for pesticide residues in imported foods has not found widespread violations, and therefore, their system has been effective in preventing foods with pesticide residues over the tolerance levels from reaching consumers. The tolerance levels for residues are set using risk assessments so that the food U.S. consumers purchase is "safe" under the provisions of the FFDCA. FDA's decision to monitor for a particular pesticide residue depends on a number of factors: whether it is likely to remain as a residue in or on food; whether the pesticide has been targeted for sampling because of a history of infractions or recent events cause FDA concern; whether the residue can be detected through multi-residue testing or single-residue testing methods; and whether FDA has resources to monitor for non-common pesticides.[36]

Critics argue that more multi-residue tests need to be developed to detect a greater number of pesticide residues and that the focus of testing should be placed on residues associated with the greatest public health consequences. Consumer fears

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[34](...continued)
Hearing on Improving the Safety of Food Imports, Statement by Raymond W. Kelly, Commissioner, U.S. Customs Service, 105th Cong., 2nd sess., 24 September 1998.

[35]Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, Hearing on Improving the Safety of Food Imports, Testimony by Dane Bernard, Vice President of Food Safety, National Food Processors Association, 105th Cong., 2nd sess., 25 September 1998.

[36]Food and Drug Administration, Center for Food Safety and Applied Nutrition, "Pesticide Program: Residue Monitoring 1996," 1 August 1998, [http://vm.cfsan.fda.gov/~dms/pes96rep.html#Table_1].

appear to focus on what they think could cause future health problems such as chronic effects of pesticide residues. FDA claims that its current system reflects a reasonable use of resources, demonstrated by the fact that each year that it has monitored import surveillance samples, few samples have been found to contain residues over the tolerance levels or have had residues for which no tolerance has been set. In 1996, the latest year for which data are available, FDA found that of 4,921 import surveillance samples, no violative residues were found in 97.4% (96.5% in 1994 and 96.8% in 1995). Fruits and vegetables accounted for 83.6% of these samples.

Testing Technologies. Testing for microbial pathogens in food can be difficult. Each pathogen/food combination requires a separate test and emerging pathogens can be difficult to recognize.[37] FDA border officials must rely on their own subjective decisions as to whether an import shipment may proceed or whether to have a sample tested. Often inspectors do not have adequate information to make a judgement based on risk priorities because, according to GAO, inspectors rely on numerical inspection targets, not risk priorities. For example, CDC experts have not traced the cause of 2,500 cases of cyclosporiasis associated with Guatemalan raspberries, although they believe that the water used by local growers remains the most likely source of the *Cyclospora* parasite.[38] Even if samples of raspberries had been tested at the border, it is probable that the pathogen would not have been found.

In addition to current funding and research under the President's Initiative, the Imported Food Safety Act of 1998 (H.R. 4080 introduced by Representative Dingell) would require FDA to fund research on the development of 60-minute tests and sampling methodologies for use in the inspection of food. The bill would have FDA test for specific pathogens: *E. coli* O157:H7, *Salmonella*, *Cyclospora*, *Cryptosporidium*, *Hepatitis A*, *Listeria*, and the presence in food of pesticide chemical residues or related residues. The bill would require that FDA submit periodic progress reports on the research and conduct the research in consultation with the other food safety agencies and the Director of the National Institutes of Health. Supporters of the bill's mandate believe that various agencies should coordinate research activities. Critics of the bill claim that there is no need to require this research because it is being carried out already in both the private sector and by the federal government.

The Food Research, Education, Safety, and Health Act of 1998 (S. 2025, introduced by Senator Coverdell) addresses the need for more research on emerging foodborne pathogens that are found in food including imported food. This bill would establish competitive research grants to study foodborne pathogens and to find the best methods to reduce or eliminate them as a threat to humans. It also would

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[37] *Listeria monocytogenes* and *E.coli* O157:H7 have only become pathogenic in the last 2 decades. Previously, FDA had found these bacteria in foods but were not alarmed by their presence.

[38] Senate Committee on Government Affairs, Permanent Subcommittee on Investigations, Hearing on the Safety of Food Imports: From the Farm to the Table — A Case Study of Tainted Imported Fruit, Testimony by Dr. Stephen M. Ostroff, CDC, 105th Cong., 2nd sess., 9 July 1998.

establish a Food Safety Council for the purpose of evaluating and establishing priorities for food safety research and education, and food-related prevention activities. (The President has acted on this suggestion by creating his Council on Food Safety in August 1998 in Executive Order 13100.) The bill would require the Council to submit an annual report to Congress on actions taken by the Council, including recommendations for improvement in food safety. It would authorize appropriations for FDA to be used to purchase testing equipment and to hire new microbiologists and inspectors to work to decrease health risks in all food including imported food.

HACCP. In the last few years both FDA and USDA have instituted a preventive approach to ensure the safety of food called the "Hazard Analysis and Critical Control Point" (HACCP) approach. USDA is phasing in HACCP for all red meat and poultry. FDA instituted HACCP for seafood products in December 1997. FDA has also published a proposed HACCP rule for all packaged fruit and vegetable juices. FDA has used a HACCP approach in its low-acid canned foods regulations for more than 20 years.

An HACCP program typically involves seven principles, based on scientific and technical knowledge. The seven principles are: (1) analyze hazards; (2) identify critical control points to control identified hazards; (3) establish the point at which a preventive action must be taken; (4) establish procedures to monitor the control points; (5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met; (6) establish procedures to verify that the system is working consistently; and (7) establish effective record keeping to document the HACCP system. Under HACCP, food companies are responsible for setting the limits of this critical step and putting in place control measures that are activated when the limits are breached. The federal government's role is to give guidance, oversee safety programs, and monitor records of those critical control points and how the company corrected problems.

Meat and Poultry Imports. Since 1996, when USDA published final regulations for an approach called Pathogen Reduction/HACCP in meat and poultry processing, all meat and poultry processors who wish to export to the United States must meet the same requirements as domestic processors. The regulation has four elements: (1) each plant had to develop sanitation standard operating procedures (SSOPs) by January 27, 1997; (2) all plants must meet performance standards and keep records that ensure the *Salmonella enterica* incidence rate is below the national baseline level established by USDA; (3) every plant must test for the bacterium *E. coli* (all strains, not specifically O157:H7) to verify that the process is controlling fecal contamination; and (4) every meat and poultry plant must develop and implement a HACCP plan to identify where hazards occur and how to prevent them. FSIS has been verifying that imported meat is processed under these regulations and penalizing violators. For example, on January 1, 1998, FSIS suspended Paraguay from exporting to this country because that country had not implemented the required pathogen reduction tests.

Seafood Imports. More than half the seafood consumed in the United States is imported. The total number of import entries for seafood each year surpasses 400,000 and are imported from 135 countries. FDA reviews about 54% of imported

seafood shipments to ensure that all meet the same safety standards as domestically produced seafood. The CDC found that shellfish caused 21 percent of all reported foodborne illnesses from 1978 to 1992. In an uncontrolled environment, such as ocean seabeds, seafood can be exposed to a wide variety of bacterial and chemical contaminants which may cause them to become a hazard to human health. The consumption of raw mollusks (mussels, scallops, clams and oysters) account for 85 percent of all the illnesses caused by eating seafood. Mollusks cause problems, in part, because most feed by filtering water through their systems, pulling nutrients out of the water in the process. In this manner, they also pick up bacteria and viruses that cause illness when eaten by people. Aquaculture seafood products can also be exposed to drugs and other chemicals in a very confined environment.

On December 17, 1997, FDA began implementing HACCP regulations mandating that processors operate state-of-the-art systems of preventive processing controls for fish products. FDA is currently in the process of inspecting all 4,100 domestic seafood processors engaged in interstate commerce for compliance with the new requirements. FDA has announced that it will inspect 1,625 seafood processors out of a total of 6,000 seafood import processors over the next year. These inspections are mandatory in that processors may not deny inspection when requested by FDA inspectors. FDA inspections are relatively new for many seafood importers. Agency officials have been quoted as saying that they are requiring importers to ensure further that their products have followed the HACCP requirements.[39] The agency is relying on assistance in inspections from state and local agencies and are training personnel to ensure consistency among the inspections.

Country of Origin Labeling

Several committees of the 105th Congress have held discussions on whether country of origin labels should be required for all imported foods in retail stores. Currently all products must be labeled or marked with a country of origin designation until a product reaches a retailer or is further processed under federal inspection. Many "natural" imported foods such as vegetables, fruits, nuts, meats, fish, and birds are exceptions. These exceptions are on a "J" list, part of Section 304 of the Tariff Act of 1930. These products, when shipped to warehouses and sold in open bins in supermarkets, do not need to be labeled as to their country of origin.

Proponents argue that consumers have a right to know where the food they are purchasing was grown. Some producers hope such labeling would give them a competitive edge in the marketplace. Opponents claim that insisting on labeling implies that the imported food is less safe and experts have shown that imported foods are not less safe than domestically produced food. They also contend that country of origin labeling has nothing to do with food safety but only adds a cost to doing business. They argue that imposing this burden on retailers could also have a negative trade impact and undermine the international harmonization efforts of the federal government.

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[39]Susan Bruninga, "FDA Rules To Prevent Hazards Causing Foodborne Illnesses Backed by Industry," *Daily Report for Executives*, No.163, Washington, D.C. Bureau of National Affairs, 24 August 1998.

Food industry groups oppose country of origin labeling, claiming that it would confuse consumers about the quality or safety of the imported products. In addition, opponents argue that these requirements fail to add any health or safety benefit to the food, but rather increase costs. Government officials reportedly have estimated that enforcement activities, plus the additional record keeping, tracking, and frequent visits to retailers would cost about $60 million for beef and lamb and between $15 million and $20 million for produce.[40]

The FY 1999 appropriation bill for USDA and FDA (H.R. 4101) directs the GAO to conduct two studies on the potential effects of mandatory country of origin labeling of imported fresh produce and of imported fresh muscle cuts of beef and lamb and to submit a report to Congress no later than 6 months after enactment of the Act. The studies are to include a cost/benefit analysis of the impact of country of origin labeling on importers, producers, processors, distributors, retailers, and consumers. The produce study will identify U.S. trading partners that currently have country of origin practices in place, the nature and scope of such practices, and a record of U.S. challenges to these requirements. It will also address the ability of the federal government and the public to respond to warnings about the outbreak of foodborne illness arising from imported produce. The beef and lamb study will also include any empirical evidence of benefit or harm to producers, processors, distributors, retailers or consumers by similar labeling programs in other countries. The final beef and lamb report shall contain a detailed statement of findings and recommendations for legislation and administrative actions. It may also consider the economic effects of exempting from eligibility for USDA quality grades imported beef and lamb including meat produced from animals imported directly for slaughter in sealed trucks and containers. The bill directs USDA to differentiate "meat produced from animals in sealed trucks and containers directly for slaughter" from "U.S. production" in all market reports.

Organization of Federal Food Safety Functions

Over time, Members of Congress have questioned whether the current monitoring and inspection systems of USDA and FDA are capable of safeguarding the nation's food supply. Reacting to news of recent foodborne illness outbreaks, Representative Fazio and Senator Durbin introduced the Safe Food Act of 1997 (H.R. 2801/S. 1465), which would transfer all food safety inspection and labeling activities to a newly created "Food Safety Administration (FSA)." In the last several Congresses, Members have proposed variations on this theme. Supporters claim reorganization will address the problem of several federal agencies performing food safety functions that, they assert, at times overlap, and at times, leave undone necessary activities to protect the public health. Supporters say that a single food safety agency could identify the most serious public health risks from specific foodborne pathogens and use resources to research testing methodologies, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or to bureaucratic "turf."

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[40]"USDA Internal Memos Warn About Country-of-Origin Labeling," *Food Chemical News*, 31 August 1998, 30-31.

However, critics believe that the time is not right for major reform of the current food safety system. Some resist the formation of a new agency because of fear that a new FSA would cause dislocation and upheaval. It could also mean that the parent agencies would have to relinquish their current budget authority and control. Many opponents to an independent agency advocate allowing the Administration's recent food safety initiative activities to take effect and allow time to determine whether these new policies reduce incidences of foodborne illnesses at the least cost. While there may be nothing in the Administration's reforms that could not be carried out by a new FSA, these critics indicate that many reforms are tailored to the statutory mandates and "cultures" of the current agencies with food safety responsibilities. From this viewpoint, the activities necessary to protect the public health may be severely strained if all were placed in a new organizational structure. Other opponents claim that the proposed legislation (H.R. 2801/S.1465) does not address the flaws in the fundamental regulatory structure for food safety created by the current statutes. It does not define a new food safety mandate. The proposed new FSA may be hindered, as are current agencies, in allocating resources to prevent the greatest hazards.

In August 1998, the National Academy of Sciences (NAS) issued a report entitled *Ensuring Safe Food from Production to Consumption.* It recommends that the federal government adopt a science-based approach to food safety and change federal statutes so that monitoring, surveillance, inspection, research, and enforcement are rooted in scientifically supportable assessments of risk to public health. It also recommends coordinating federal food safety agencies by establishing a unified, central framework for managing food safety programs headed by one official with control of resources for all federal food safety activities. NAS believes such a unified approach could allow U.S. officials to undertake more cooperative inspection activities within other countries. It also could set policies that only allow food imports from countries with food safety standards deemed equivalent to U.S. standards.

Appendix A

FDA Enforcement of Regulations on Imported Foods

FDA has responsibility for ensuring that a large variety of imports meet U.S. requirements for safety. Tables A-1 and A-2 show types of food imported during FY 1997 and the percentage of food shipments (called line entries by FDA) that FDA inspectors examined.

FDA considers that through periodic examinations it can enforce U.S. safety requirements on food. These examinations are the responsibility of district offices and resident posts. Also FDA works with Customs at 330 points of entry, including airports. When food entries arrive at remote locations, FDA relies on Customs officials to help identify suspicious products. FDA uses information for import surveillance developed by state regulatory agencies to better design its import coverage or take enforcement action when appropriate. At times, state inspectors examine foods once they are in the market and share information with other federal and state regulators.

FDA has a series of categories for problems under which it records the type of problem found with imported foods. Through examinations FDA finds these problems in food entries, collectively called "adulteration" under the statute, and detains them. (See Table A-3.) The "filth" category has the most violations; it covers insect, rodent droppings, and other contamination. (See Table A-4.) Microbiological hazards such as bacteria and viral pathogens are second in rates of violations. Pesticide residues cause problems because there are either no established tolerances for the specific pesticide/food combination or the residue is over the permitted tolerance level. When FDA officials find food entries "misbranded" or mislabeled, often it is because the label either does not reflect the contents in the package in English or correctly lists the ingredients in the package. Both problems (adulteration and misbranding) can sometimes be corrected by some type of reconditioning such as cleaning the produce or commodity by the importer/shipper, cooking products, and/or relabeling the contents.

FDA uses several regulatory approaches and legal instruments to get importers to comply with the FFDCA. The major regulatory instrument FDA uses is detention. The agency also uses warning letters, recalls, and sanctions such as seizures, injunctions, and/or prosecutions.

Detention Without Physical Examination. If FDA finds violative shipments of health significance (e.g., samples of food line entries with microbial contamination such as *Salmonella, E. coli,* and *Staphylococci aureus* in soft cheeses) in the imported food, FDA may place subsequent shipments of food from that particular country of origin, shipper, or responsible firm under a category called "detention without physical examination (DWPE)." DWPE is the administrative act of detaining an entry of a specified article without physically examining it on the basis of information regarding past violative history and/or other information indicating

that the product may be violative.[41] When a product, importer, country of origin, etc. is placed on DWPE, all ports of entry are alerted with a notice called an import alert.

These "import alerts" tell each FDA inspector to inspect and analyze the product at the border, or to automatically detain the product among other actions until further examinations can verify its admissibility.[42] For example, last year "import alerts" were sent out warning about *Salmonella* found in seafood, aflatoxin found in marzipan (a candy), and peanut confections from a firm in Mexico.

A single violation of health significance may cause a DWPE designation. For example, a product that contains actionable levels of a pesticide residue, a mycotoxin (a harmful bacteria), or a chemical contaminant could be detained.[43] In other cases, FDA may wait for several violations before invoking DWPE if the problem is less significant or it believes more evidence of a problem is needed before taking action.

Shippers or individual importers can petition to have their products removed from DWPE by having a foreign government certify that it has instituted a program to assure that future shipments will be in compliance with the FFDCA and will be monitored by the exporting country; or an individual importer may use a commercial laboratory to test the next several shipments and then submit the laboratory's certificates of analyses to FDA to prove that the product is in compliance. If all shipments are found in compliance, the importer can ask to have that product-producer-country of origin removed from the automatic detention list. However, FDA, at a minimum, still reviews all certificates to make sure that the laboratories are providing valid certificates. FDA reviews the documentation provided by the importer and/or laboratory. In addition, FDA at times duplicates the analysis to be sure the results have been accurately reported and reviews the technical expertise of the laboratory to do the analysis.

GAO has criticized FDA's policy of allowing importers to choose their own laboratories to select samples and perform tests, concluding that FDA opens the doors to the possibility of approving the entry of unsafe products on the basis of falsified test results.[44] GAO found that some importers share shipments that have

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[41]Food and Drug Administration, Regulatory Procedures Manual, Chapter 9, Import Operations/Action, Subchapter, Automatic Detention, (August 1995), 345.

[42]FDA may take enforcement actions when a food entry is unsatisfactory. For example, to prevent what is known as "port shopping" by the shipper/firm, FDA notifies other ports of entry by issuing import directives. "Port shopping" is a term used by regulators to refer to shippers of imported foods that look at other ports of entry for their shipments to avoid scrutiny and attendant delays. These directives are called bulletins or import alerts. "Bulletins," which expire in 90 days, often contain information from another governmental agency, a foreign government, or a competitor.

[43]FDA stopped all imports of canned mushrooms from China after an epidemiology report from the CDC showed an outbreak of illness due to *staphylococcal enterotoxin* associated with canned mushrooms from China. FDA resumed a lot-by-lot release after 19 Chinese mushroom factories had been inspected.

[44]General Accounting Office, *Food Safety: Federal Efforts To Ensure the Safety of Imported*
(continued...)

already been tested so samples are found in compliance. FDA, since March 1998, has instituted guidelines on the review of test results prepared by private laboratories.

Warning Letters. Letters are issued to importers or their agents, for a number of reasons: i.e., if FDA finds that an importer has not held the food shipment pending receipt of an FDA release notice; if the line entry contains misleading or inaccurate information; if FDA cannot locate the product to be sampled; or if there are repeated attempts to import foods that come under the category of "detained without physical examination."

Requests for Voluntary Recalls. FDA asks an importer to voluntarily recall an import when a potential health hazard is found in the food or when there is evidence that the food was distributed that should have been detained or refused admission.

Sanctions. FDA may recommend seizing the product. Seizures are actions taken against an imported food where FDA must show through laboratory analysis that the food violates the FFDCA. FDA only takes these actions if the food represents a potential hazard to health, would likely be distributed rather than detained, re-exported, or destroyed; has been fraudulently identified in submitted documents; or FDA had previously refused its entry. In addition, FDA may recommend that an importer be criminally prosecuted by the Justice Department, or that the importer be enjoined, or forbidden from offering future violative shipments for entry, or that the importer forfeit the bond. Customs regulations allow for forfeiture of either the bonded amount or more (up to three times the bonded amount). The only other official sanction is pursuing criminal charges in federal court. In most cases, FDA relies on forfeited bonds to deter importers who fail to follow the rules. Each year perhaps two or three egregious cases may be pursued in court.

GAO argues that some shippers substitute cargo that was en route to a holding area and do not meet FDA's request that a shipment be redelivered to the Customs for disposition or that importers substitute shipments. GAO presumes that these products have entered commerce. GAO has questioned whether bond forfeiture effectively deters illegal distribution of imported foods.

GAO concluded that FDA's enforcement system is vulnerable to unscrupulous importers and that the importers' bonds are ineffective deterrents against attempts to market contaminated products. FDA's response to these comments is that it cannot physically inspect the destruction or export of every refused shipment and that it targets inspections to shipments from importers posing the greater risk of noncompliance. Customs officials stated that current penalties are adequate in most cases.

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[44](...continued)
Foods Are Inconsistent and Unreliable, GAO/RCED-98-103, April 1998, 37.

Table A-1. Imported Food Line Entry Data, Fiscal Year 1997

Categories of Imported Foods	Total line entries	Entries may proceed	Entries reviewed by FDA	% of total that were allowed to proceed	% of total FDA reviewed
Whole/Milled Grains and Starch	60,923	43,303	17,620	71%	29%
Bakery Products/ Dough/ Ices	144,223	76,991	67,232	53%	47%
Macaroni & Noodle Products	42,536	10,815	31,721	25%	75%
Cereal Preparations/Breakfast Food	11,268	7,314	3,954	65%	35%
Snack Food Items	10,820	4,520	6,300	42%	58%
Milk, Butter, Dried Milk Products	7,334	3,648	3,686	50%	50%
Cheese & Cheese Products	49,238	5,650	43,588	11%	89%
Ice Cream & Related Products	1,650	759	891	46%	54%
Filled/Imitation Milk Products	225	78	147	35%	65%
Egg & Egg Products	1,384	89	1,295	6%	94%
Fishery/Seafood Products	401,418	183,294	218,124	46%	54%
Meat, Meat Products, Poultry	3,924	2,615	1,309	67%	33%
Vegetable Protein Products	3,791	1,048	2,743	28%	72%
Fruits & Fruit Products	289,244	170,339	118,905	59%	41%
Nuts & Edible Seeds	24,912	13,054	11,858	52%	48%
Vegetable & Vegetable Products	608,961	320,518	288,493	53%	47%
Vegetable Oils	28,995	19,675	9,320	68%	32%
Dressings & Condiments	15,476	3,934	11,542	25%	75%
Spices, Flavors & Salts	69,176	22,920	46,256	33%	67%
Soft Drinks & Waters	64,735	47,181	17,554	73%	27%
Beverage Bases	10,880	2,841	8,039	26%	74%
Coffee & Tea	59,526	42,644	16,882	72%	28%
Alcoholic Beverages	293,393	268,724	24,669	92%	8%
Candy without Chocolate/Gum	41,210	16,012	25,198	39%	61%
Chocolate & Cocoa Products	34,961	16,640	18,321	48%	52%
Gelatin, Rennet, Pudding Mix, Pie Fill	7,419	2,559	4,860	34%	66%
Food Sweetener (Nutritive)	17,911	12,077	5,834	67%	33%
Multiple Food Dinner, Specialties	30,565	5,101	25,464	17%	83%
Soups	17,322	6,008	11,314	35%	65%
Prepared Salad Prod. w/o Seafood	889	214	675	24%	76%
Baby (Infant/Junior) Food Products	2,752	162	2,590	6%	94%
Dietary Conventional Food	3,178	1,742	1,436	55%	45%
Food Additives (For Human Use)	23,624	3,365	20,259	14%	86%

Categories of Imported Foods	Total line entries	Entries may proceed	Entries reviewed by FDA	% of total that were allowed to proceed	% of total FDA reviewed
Color Additive (Food, Drug, Cosmetic)	2,412	716	1,696	30%	70%
Miscellaneous Food Related Items	338,337	201,352	136,985	60%	40%
Vitamin, Mineral, Protein, unconventional dietary specialties for humans/animals	40,936	510	40,426	1%	99%
TOTAL	2,765,548	1,518,412	1,247,136	55%	45%

Source for Tables A-1 through A-4: Barbara Friedman, Food and Drug Administration, Email message, 15 July 1998.

Table A-2. Imported Foods Examined, Fiscal Year 1997.

Categories of Imported Foods	Examinations[1]			Total Exam-ined	% of Total[2] Line Entries Examined
	Field Exams of Lots	Samples Physically Analyzed	Detention without Physical Examination		
Whole/Milled Grains and Starch	361	362	124	847	1%
Bakery Products/Dough/Ices	1,100	523	73	1,696	1%
Macaroni & Noodle Products	1,034	590	204	1,828	4%
Cereal Preparations/Breakfast Food	53	46	0	99	1%
Snack Food Items	256	174	6	436	4%
Milk, Butter, Dried Milk Products	118	41	9	168	2%
Cheese & Cheese Products	446	613	246	1,305	3%
Ice Cream & Related Products	18	15	0	33	2%
Filled/Imitation Milk Products	11	4	0	15	7%
Egg & Egg Products	35	48	2	85	6%
Fishery/Seafood Products	4,882	4,451	2,463	11,796	3%
Meat, Meat Products, Poultry	2	10	3	15	0%
Vegetable Protein Products	27	12	2	41	1%
Fruits & Fruit Products	2,164	2,896	1,078	6,138	5%
Nuts & Edible Seeds	490	459	223	1,172	5%
Vegetable & Vegetable Products	3,708	3,405	2,874	9,987	3%
Vegetable Oils	30	52	7	89	0%
Dressings & Condiments	198	155	249	602	4%
Spices, Flavors & Salts	756	491	489	1,736	3%
Soft Drinks & Waters	201	121	21	343	1%
Beverage Bases	169	136	27	332	3%

Categories of Imported Foods	Examinations[1]			Total Exam-ined	% of Total[2] Line Entries Examined
	Field Exams of Lots	Samples Physically Analyzed	Detention without Physical Examination		
Coffee & Tea	362	40	4	406	1%
Alcoholic Beverages	1	8	1	10	0%
Candy without Chocolate/Gum	1,582	556	62	2,200	5%
Chocolate & Cocoa Products	266	128	445	839	2%
Gelatin, Rennet, Pudding Mix, Pie Filling	148	43	9	200	3%
Food Sweetener (Nutritive)	77	66	2	145	1%
Multiple Food Dinner, Specialties	733	342	109	1,184	4%
Soups	307	81	39	427	2%
Prepared Salad Products w/o Seafood	2	9	4	15	2%
Baby (Infant/Junior) Food Products	39	7	13	59	2%
Dietary Conventional Food	16	4	0	20	1%
Food Additives (For Human Use)	41	20	14	75	0%
Color Additive (Food, Drug, Cosmetic)	5	2	7	14	1%
Miscellaneous Food Related Items	1,403	701	227	2,331	1%
Vitamin, Mineral, Protein, Unconventional Dietary Specialties for Humans/Animals	545	118	97	760	2%
TOTAL	21,586	16,729	9,133	47,448	1.7%

[1] Sample analysis and field exam data were retrieved from the Program Oriented System (PODS) Field Information System (FIS). Field exams were formally referred to as wharf exams and are counted by lots. "Detentions without physical examination' were formally referred to as "automatic detentions."

[2] See Table A-1 for total of line item entries.

Table A-3. Number of Detentions, Imported Foods, Fiscal Year 1997

Categories of Imported Foods	Total Regular Detentions[1]	Total Detentions Without Physical Examinations[2]	Total All Detentions
Whole/Milled Grains and Starch	7	0	7
Bakery Products/Dough/Ices	68	6	74
Macaroni & Noodle Products	15	9	24
Cereal Preparations/Breakfast Food	75	246	321
Snack Food Items	4	0	4

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Categories of Imported Foods	Total Regular Detentions[1]	Total Detentions Without Physical Examinations[2]	Total All Detentions
Milk, Butter, Dried Milk Products	3	0	3
Cheese & Cheese Products	6	2	8
Ice Cream & Related Products	1,480	2,463	3,943
Filled/Imitation Milk Products	11	3	14
Egg & Egg Products	4	2	6
Fishery/Seafood Products	250	132	382
Meat, Meat Products, Poultry	307	917	1,224
Vegetable Protein Products	20	29	49
Fruits & Fruit Products	984	2,079	3,063
Nuts & Edible Seeds	19	7	26
Vegetable & Vegetable Products	267	738	1,005
Vegetable Oils	65	21	86
Dressings & Condiments	51	27	78
Spices, Flavors & Salts	97	4	101
Soft Drinks & Waters	5	1	6
Beverage Bases	236	62	298
Coffee & Tea	86	445	531
Alcoholic Beverages	34	9	43
Candy without Chocolate/Gum	20	2	22
Chocolate & Cocoa Products	231	109	340
Gelatin, Rennet, Pudding Mix, Pie Filling	61	39	100
Food Sweetener (Nutritive)	8	4	12
Multiple Food Dinner, Specialties	12	13	25
Soups	12	0	12
Prepared Salad Prod. w/o Seafood	9	9	18
Baby (Infant/Junior) Food Products	2	5	7
Dietary Conventional Food	0	0	0
Food Additives (For Human Use)	12	7	19
Food Additives (For Human Use)	85	227	312
Miscellaneous Food Related Items	5,405	9,052	14,457
TOTAL	10,333	17,681	28,014

[1]Regular detentions were formally referred to as detentions with physical examination or non-automatic detentions.
[2] Detentions without physical examination were formally referred to as automatic detentions.

NOTE: Line entry data retrieved from the OASIS System.

Table A-4. Reasons for Detentions of Imported Foods, Fiscal Year 1997

Categories of Problem Areas[1]	Regular Detentions[1]	Total Detentions without Physical Exam[2]	Total Detentions
Approvals - Drug & Device	46	2	48
Acidified & Low Acid Food Exams	129	659	788
Net Contents & Fill of Container	28	0	28
Colors in Foods & Cosmetics	205	214	419
Decomposition of Foods	499	751	1,250
Economic Deception—All Products Including Health Fraud	33	42	75
Food Additives	139	748	887
Standard of Identity for Foods	10	0	10
Standard of Quality for Foods	10	1	11
Filth—all areas	1,787	4,260	6,047
Hazardous Conditions	1	5	6
Labeling—All problems complying with the Fair Packaging and Labeling Act and Nutrition Labeling and Education Act	1,663	76	1,739
Metals in All Products — Seafood and Dinnerware	124	903	1,027
Microbiological Hazards—Bacteria and Viral Pathogens Found	511	2,702	3,213
Mycotoxin—Mold Toxins	12	39	51
Nutrition Analysis	146	0	146
Pesticides Residues	138	1,966	2,104
Registration & Listing All	1,512	10	1,522
Total Detentions	5,456	9,133	14,589

[1] Food can be detained for more than one problem; the sum of the foods recorded in problem areas may be greater than the total number of detentions.

[2] Formerly, regular detentions were referred to as "detentions with physical examination" or "non-automatic detentions;" detentions without physical examination were referred to as "automatic detentions."

Appendix B

International Trade Agreements and Food Safety

In the last several decades, food trade has increased worldwide, particularly for the United States. Import tariffs, which for many years restricted much of this trade, have now given way, at times, to nontariff barriers that are used as obstacles to all types of trade including trade in foods. Measures that protect the health and safety of foods — food safety measures — can be legitimately applied under international rules. However, in some instances, these measures have become one way by which countries can disguise measures to protect their domestic agricultural industries from competing imports. In 1995, the United States signed an agreement that established the World Trade Organization (WTO).[45] In becoming a party to the WTO, the United States, and all other WTO members, were required to become parties to a number of other multilateral trade agreements containing rules or disciplines by which member countries, including the United States, pledge to conform as they establish or modify domestic regulations.[46]

SPS Agreement

One discipline is the "Agreement on the Application of Sanitary and Phytosanitary Measures"(SPS Agreement) that applies to all sanitary (human and animal health) and phytosanitary (plant health) measures that may have a direct or indirect impact on international trade. SPS measures are laws, decrees, standards, regulations, guidelines, and procedures that protect human, animal, or plant life or health primarily from all types of risks.[47] These risks arise from additives, contaminants, toxins, or diseases in foods, animals or plants. SPS measures can take many forms such as: requiring products to come from a disease-free area, inspection of imported products, specific types of processing for specific products, the setting of allowable maximum levels of pesticide residues, or restrictions on additives in food. The SPS Agreement recognizes the right of countries to maintain SPS measures but, at the same time, it tries to prevent the use of SPS measures from being used as

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[45]The World Trade Organization (WTO) is the successor organization to the General Agreement on Tariffs and Trade. The WTO was established on January 1, 1995, as the common international institutional framework for the conduct of trade relations among its members in matters related to the Uruguay Round Agreements. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act, [P.L.103-465] signed by the President on December 8, 1994.

[46]The Administration discussion of this agreement can be found in Uruguay Round Agreements Statement of Administrative Action, H.R. Doc. No. 316, 103rd Cong., 2nd sess., vol. 1 (1994), 742-56.

[47]SPS measures include: end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labeling requirements directly related to food safety.

nontariff barriers to trade.[48] The rules and disciplines ask that domestic SPS measures not be arbitrary nor restrict trade any more than necessary to achieve their SPS objective; that they be based on scientific principles and the assessment of risk; that there be work towards harmonization through the greater use of international standards, that countries can achieve the same level of protection — equivalency — even though SPS measures can differ; that measures be transparent in that member countries let their standards be known to all interested parties; and that countries adapt their policies to recognize pest and disease-free regions.[49]

The text encourages countries to make their SPS standards compatible or equivalent but not at the expense of the trading partner's chosen level of protection. Equivalency recognizes that different measures may lead to the same level of health protection. Thus, where it can be demonstrated that an exporting country has an equivalent health or safety system, the importing country should allow access for the affected product. However, the importing country is not required to accept the exporting country's health and safety measures as equivalent if the importing country has a scientific basis for disagreeing that there is equivalency. While international standards can be used by countries working towards compatibility or equivalence, the pursuit of equivalence should not reduce the level of protection of human, animal or plant life or health.

The text of the WTO Agreement maintains the rights of states and local governments in the United States to establish SPS measures. There would be no federal preemption over a state's right to protect the health and safety of its citizens. However, should a state's measure be challenged in a trade dispute, the state would have to rely on federal officials to present the measure's basis before a dispute settlement panel.

The WTO Agreement allows members to use the WTO dispute resolution process to settle disputes arising under it. In addition, the SPS Agreement itself contains provisions allowing a dispute settlement process that has some opportunity for the airing of scientific evidence. If a trade dispute is not resolved in the consultation process, the complaining party can ask for a panel composed of five non-governmental people trained in international law or policy drawn from the disputing countries or in the case of the panel chairman, from another country. There will be an agreed roster of such people, but the disputing parties may also agree to use other non-governmental people on panels. If the panel so decides, it can establish a scientific review board either at the request of one of the disputing parties or on its own motion (if it does not have the scientific expertise in the matters under dispute) unless all disputing parties consider the board to be unnecessary. In disputes,

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[48]The language of the SPS Agreement caused controversy because in some parts, the text does not specifically define what is meant; it was deliberately left to be interpreted. This means that the meaning of some of the language as applied to specific situations may only become clear if and when GATT panels rule on these trade disputes. By accepting the Agreement, governments agree to be bound by its rules.

[49]For additional information see Congressional Research Service, *Sanitary and Phytosanitary Safety Standards for Foods in the GATT Uruguay Round Accords*, by Donna U. Vogt, CRS Report 94-512 SPR, 24 June 1994.

defending countries can justify their measure if they can demonstrate that their measure meets relevant international standards, like those established by multilateral standard setting organizations (see below), and/or if they are deemed to be necessary to protect human, animal, or plant life or health, and/or are presumed to be consistent with the relevant provisions of the Agreement. If a country's standards are more stringent, the country must present scientific evidence demonstrating the need for a more stringent or higher level of protection. A country can choose to keep the measure; it cannot be forced to change its SPS measures. Instead, a country can pay compensation or suffer retaliation.

The thrust of the SPS Agreement is harmonization of standards governing foods. Harmonization of standards depends on the mutual recognition of comparable standards employed by member states. Harmonization also depends on reducing differences among countries' health and safety standards when those differences are not justified by science.

Multilateral Standard Setting Organizations

Both the North American Free Trade Agreement (NAFTA) and the Uruguay Round Agreements require that each member country base its SPS measures on the standards, guidelines and recommendations of three international standard setting organizations. These organizations, the Codex Alimentarius Commission (Codex); the International Office of Epizootics (OIE); and the International Plant Protection Convention (IPPC) in cooperation with the North American Plant Protection Organization (NAPPO), have official member country experts and scientists as delegates. The SPS Agreement suggests that member countries, when disputing over an SPS measure, use the technical expertise of these organizations to provide advice for judging trade actions in dispute settlements. The U.S. government supports the use of international standards in settling disputes because such standards could assist U.S. regulatory agencies to ensure that imported foods meet U.S. standards when the food imports come from another member country.

Some consumer groups support the standard setting process of these international organizations. They have asked, however, for a seat at the forum where decisions are made; so far they have only been permitted to attend general meetings. The groups claim that they want to use every opportunity to increase the health and safety of traded foods before they are offered for import into the United States. One group, the Center for Science in the Public Interest (CSPI), is advocating that Codex establish procedures for obtaining consensus on standards to allow nations to block more easily the adoption of Codex standards that fall below domestic regulatory requirements.[50]

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[50]CSPI also does not want Codex standards that permit the use of food additives not approved by FDA, or permit levels of lead in fruit juices and milk that are higher than those set by FDA. "CSPI Calls for Careful Scrutiny of Codex Procedures," *FDA Week*, 4 September 1998, 6.

Codex Alimentarius Commission

The Codex Alimentarius Commission's purpose is to protect the health of consumers everywhere and to facilitate international trade in foods. It was created in 1962 by the United Nations's Food and Agriuclture Organization and the World Health Organization. The Commission has 158 member countries and conducts its work through working parties or committees.[51] The United States has one vote in the deliberations of the Codex, usually cast (when not delegated) by the head of the U.S. delegation (currently Dr. F. Edward Scarbrough, U.S. Manager for Codex Alimentarius, Office of the Under Secretary for Food Safety, USDA) who represents the U.S. government. Other official participants in U.S. delegations come from other federal agencies, FDA and EPA. Industry, consumer organizations and international scientific and food technology organizations send observers to Codex meetings as non-governmental organizations. To qualify as a non-governmental organization, an organization must operate in more than two countries to obtain Codex recognition as a participating non-governmental organization. CSPI has been recognized as an official observer to Codex meetings.

Codex is the only international organization in the field of foods that has representatives from industry, academia, and government. Its standards are unique in that they are globally developed on the basis of the best scientific and technical advice. The work is conducted in subsidiary bodies.[52] To facilitate international trade in foodstuffs, Codex meets every 2 years and adopts standards. The adoption process for approving standards has eight formal steps. Table C-1 lists the eight steps.

There are two expert committees in Codex that have completed extensive work on food additives and pesticide residues. The first is the Joint FAO/WHO Expert

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[51]Codex codes help prevent the dumping of unsafe, poor quality foods on other countries by requesting countries to alert one another after an entry has been refused for quality reasons. Another set of Codex standards ensure that the composition of foods is easily identifiable. For example, it sets the standard that peanut butter is made from peanuts. A standard for honey (one of the sugar standards) helps less developed countries compete on world markets by lending assurance of a product's identity and general comparability with products of developed countries. Unfortunately, the process established by this system takes years to complete.

[52]These include regional coordinating committees, commodity committees, and general subject matter committees. An executive committee of the Commission is responsible for making recommendations about the general direction of the Commission's work. Eighteen commodity committees (sometimes known as vertical committees) develop standards and codes of practice for specific commodities such as fresh fruits and vegetables, sugars, cocoa products and chocolate, etc. There are eight committees known as the horizontal committees that focus on general issues: i.e., food labeling, food additives and contaminants, food hygiene, food import and export inspection and certification systems; residues of veterinary drugs in foods, and general principles. Their work is to establish general standards for food. General Accounting Office, *Agriculture Trade Agreements: Selected Implementation Issues*, Statement for the Record by JayEtta Z. Hecker, Associate Director, International Relations and Trade Issues, National Security and International Affairs Division, GAO/T-NSIAD-98-106, 12 February 1998.

Committee on Food Additives (JECFA) and it deals with food additives that are defined as follows:

> ...any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

A second committee is known as the Joint FAO/WHO Meetings on Pesticide Residues (JMPR). The JMPR recommends to the Codex Committee on Pesticide Residues (CCPR) the international maximum residue limits for pesticides in food (Codex MRLs).[53] An MRL is similar to a U.S. tolerance. It is the maximum amount of a pesticide residue permitted to be left on a food or feed crop after the use of a pesticide according to good agricultural practices (GAP).[54] Even after the Codex 8-Step process has been completed (see below), member countries still must officially adopt the standards as recommended.

Member countries in Codex recognize that inspecting at the point of import does not provide the most productive protection measures for food safety. Rather countries are instituting quality control systems such as HACCP to assure food quality and safety throughout the food chain. The government regulatory authorities can monitor and control the process to ensure that control procedures are adequate. Codex is currently developing guidance documents to help member countries evaluate whether import or export control measures, or other food safety measures of other countries are equivalent to their own. Trade becomes easier if and when each country recognizes and accepts the protection system of the trading partner.

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[53]Introducing Codex Alimentarius. Prepared by the Secretariat of the Joint FAO/WHO Food Standards Program. Rome, Italy. 1990. p. 17.

[54]Secretariat of the Joint FAO/WHO Food Standards Program, Food and Agriculture Organization, Rome, Italy. Part I. Recommendations to Governments Concerning the Implementation of the Recommended National Regulatory Practices and the Acceptance of Codex Maximum Limits for Pesticide Residues. J.R. Wessel, Chairman of the Ad Hoc Working Group on Regulatory Practices. November 1985. CAC/PR-9 1985.

Table C-1. The Codex Procedure for the Elaboration of Worldwide and Regional Codex Standards

Step 1	The Commission decides to elaborate a standard and assigns the work to a committee. A committee can also suggest to the Commission that work be done on a specific standard.
Step 2	The Secretariat (of Codex) arranges preparation of a "Proposed Draft Standard."
Step 3	The Proposed Draft Standard is sent to member governments and international organizations for comment. (It is circulated widely among interested parties in industry, academia, and environmental groups.)
Step 4	The Committee discusses the proposed standard and forwards comments to the Commission.
Step 5	The Proposed Draft Standard is sent to the Commission/ Executive Committee through the Secretariat for adoption as a Draft Standard.
Step 6	The Draft Standard is sent (again) to governments and international organizations for comment.
Step 7	The Secretariat forwards comments to the Committee where they are discussed.
Step 8	The Draft Standard is returned to the Commission for adoption as a Codex Standard to be sent to member governments for acceptance.

Source: Introducing Codex Alimentarius. Prepared by the Secretariat of the Joint FAO/WHO Food Standards Program. Rome, Italy. 1990. p.12. Also see [http://www.fao.org/WAICENT/faoinfo/economic/esn/codex/proced1.htm].

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 4

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 15 1998

The Honorable Susan M. Collins
Chairman, Permanent Subcommittee
on Investigations
Committee on Governmental Affairs
United States Senate
Washington, D.C. 20510-6250

Dear Madam Chairman:

Thank you for your letter of August 12, 1998 requesting the Food and Drug Administration's (FDA) comments on a summary analysis of FDA's regulatory and legal authority for imported foods.

Generally, we agree with the description as written. Specifically, we have provided an annotated version of the document showing clarifications or comments on the material presented. Because we assume this document may be the basis for a discussion of our authority, we believe that it is important that it be precise, and fairly and accurately reflect the statute, regulations and relevant policies.

In particular, we call your attention to the assertion in Section I.C., that FDA's designation of products on the Detention Without Physical Examination (DWPE) listing effectively halts the specified importers from shipping adulterated and misbranded foods. We disagree. FDA has found that entries of products designated as DWPE continue to be presented for import. For entry approval, however, the importers are required to present evidence that the DWPE product complies with the law (i.e., that the product is not violative).

As you know, FDA's authority over imported foods differs from our authority over domestic products because the Agency cannot compel the inspection of the source of production for imports. The summary you provided describes FDA's import authority as "broader" than our domestic authority. While we agree the authorities differ, in practice, the scope of our inspection authority is actually much greater for domestic products because we can require the inspection of domestic production facilities.

As you and the General Accounting Office (GAO) have noted, FDA's current authority over imported foods is premised in large part on our stopping unlawful products at the border. We

believe that sampling at the border and testing all foods offered for import is no longer practical given the annual escalation in the number of imported food entries and the Agency's increasingly stressed resources. The perishable nature of many imports and the impracticality of testing these products for all potential pathogens before the product loses its marketability similarly demonstrates that inspection and testing at the point of entry is no longer a practical method of control to ensure safety. For this reason, the Administration has proposed (introduced as S. 1707 and H.R. 3052) to amend the Federal Food, Drug, and Cosmetic Act to provide FDA with authority to help ensure that foods offered for import into the U.S. meet U.S. food safety requirements or otherwise achieve the level of protection required for comparable domestic foods. Under the bills, FDA would be permitted to consider the systems, conditions, and measures under which an imported food was produced and handled.

We also note that the summary comparison of FDA and the U.S. Department of Agriculture (USDA) authority you provided cites USDA's authority over imported meat and poultry products that includes the requirement that such products be produced under conditions that provide the same level of protection to those in the United States. As mentioned above, the Administration has determined that FDA should have comparable authority.

We look forward to your hearing of September 24 to discuss additional recommendations to improve the safety of imported foods. In the interim, if you have further questions, or need additional information, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

SUMMARY OVERVIEW OF FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE JURISDICTION OVER IMPORTS

(annotations by FDA, September, 1998)
(*italics* = *addition*; [ ] = deletion)

I. FOOD AND DRUG ADMINISTRATION (FDA) AUTHORITY OVER THE IMPORTATION OF FOODS INTO THE U.S.

Under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA has the authority *under certain circumstances defined by statute to refuse admission of imported* [to halt at the border imports of] food and all other FDA-regulated products. The systems FDA currently has in place can be [effectively] utilized to stop individual shipments, all shipments from particular manufacturers, and even shipments of all designated products from *a particular country or* [whole] countries. *FDA comment: Currently the effectiveness of FDA's current systems and authority is under review by the Permanent Subcommittee on Investigations, GAO, and FDA, and generally there is agreement that system effectiveness would be improved by legislation to permit FDA to consider the level of protection provided at the point of production for imported foods.*

A. Joint FDA-U.S. Customs Service Statutory Authority To Regulate the Importation of Foods Into the U.S.

The U.S. Customs Service has jurisdiction over all [articles] *items offered for* import[s] into the United States, whether FDA-regulated or not. The power to [stop] *refuse admission of* shipments of FDA-regulated articles is therefore jointly held by the FDA and the Department of the Treasury. FFDCA Section 801 provides in pertinent part as follows:

> The Secretary of the Treasury {in the administration of the customs laws of the United States} shall deliver to {FDA}, upon {the agency's} request, samples of food . . . being imported or offered for import. . . If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or (2) such article is forbidden or restricted in sale the country in which it was produced or from which it was exported, or (3) such article is adulterated {or} misbranded . . . then such article shall be refused admission.

21 U.S.C. § 381(a). (Attachment A).

Because FDA does not have explicit authority to inspect foreign production facilities, but can inspect domestic production facilities [It is important to note that] the statute grants FDA the authority to *refuse admission of* [deny entry to] a food product if the product [merely] "appears" to be in violation of *certain provisions of* the FFDCA -- the agency need not [prove] *establish* an actual violation in order to *refuse admission* [prevent entry]. This authority *to refuse admission* [is significantly broader than] *differs from* that exercised by FDA with respect to food products [within the U.S.; for products] in *domestic commerce, where* [the U.S. commercial stream] FDA must [actually prove] *establish by a preponderance of the evidence that* the product *is or may have become* adulterated or misbranded [in some manner] in order to *seize it* [to halt its distribution].

Food *offered for import* which *is refused admission* [appears to be adulterated or misbranded] must be destroyed unless the article is exported (under regulations prescribed by the Department of the Treasury) within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. 21 U.S.C. § 381(a). It has long been held by the courts that the Customs Service must accept FDA's determination as to whether a food (or other FDA-regulated article) appears adulterated or misbranded. *See Sugarman V. Forbragd*, 405 F.2d 1189 *1190* (9th Cir 1968).

While a decision is being made as to whether to permit importation of a food product, the importer may secure a bond to retain possession of the food to be imported. 21 U.S.C. § 801 (b). The bond must provide for the payment of liquidated damages in the event of default. *Id. Bonds under 801(b) are Customs single entry or term bonds, which contain a condition of redelivery upon Customs' demands. 21 CFR 1.97.* If it appears to FDA that an article can be relabeled or reconditioned so as to be brought into compliance with the FFDCA, the final determination to admit the article may be deferred. *Id.* To secure a deferral, the importer must file a written application and execute a *redelivery* bond. Reconditioning, relabeling or destruction *after refusal* of the imported food must be performed under FDA or Treasury's supervision. *Id.* All expenses for the reconditioning or destruction of the food must be paid by the importer. *Id.*

B. Joint FDA-U.S. Customs Service Authority To Promulgate Regulations Implementing FFDCA Import Provisions

FFDCA Section 701*(a)* [generally] provides the Secretary of Health and Human Services with the authority to promulgate regulations *for the efficient enforcement of* [and hold hearings under] the Act. This authority has generally been delegated to FDA. Section 701(b) *contains a particular provision regarding import regulations; it* [specifically] provides, in pertinent part, as follows:

> The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

21 U.S. *C.* § 371(b). It should be noted that it is the Secretary of Health and Human Services *(and by delegation FDA)* alone who determines when such regulations should take effect.

FDA has promulgated [administrative] regulations setting forth procedures for the importation of articles into the U.S. These regulations provide for:

- notice of sampling;
- payment to owners or consignees for samples;
- the grant of a hearing should an article appear subject to refusal of admission;
- application for authorization to relabel or recondition product;
- grant of authorization to relabel or recondition product;
- bonds; and
- costs charged by FDA in supervising relabeling or reconditioning of product.

21 C.F.R. §§ 1.83 - 1.99. (Attachment B).

Under a 1979 Memorandum of Understanding (MOU) between the U.S. Customs Service and FDA, FDA is also delegated the authority from *Customs* [the Treasury Department] to collect samples, issue notices of sampling, and issue notices of refusal of admission. FDA Compliance Policy Guide 7155g.03 (August 14, 1979) (Attachment C). Under the MOU, designated FDA officers are authorized as Customs Officers. The delegation of authority is pursuant to Section 401(i), of the Tariff Act of 1930, 19 U.S.C. § 1401(i), as well as a 1954 Treasury Delegation Order 165 (T.D. 53645, 19 FED. REG. 7,241).

C. FDA [Automatic] Detention without Physical Examination

FDA has implemented its statutory authority through a [system] *procedure* known as ["automatic] detention *without physical examination (previously known as "automatic detention")*. FDA Regulatory Procedures Manual (RPM), Chap. 9 at 346-353 (Aug. 1995) *(there is a 1997 edition)*. (Attachment D). The ["automatic detention" system] *procedure* is not set forth in FDA regulations; rather, all of FDA's requirements for governing the importation of foods into the U.S. *are* set forth *as* [regulatory] guidance. [FDA routinely asserts that regulatory] Guidances such as those contained in the RPM are not subject to notice-and-comment rulemaking under the Administrative Procedure[s] Act. *(Importantly, however, FDA has recently established Good Guidance Practices, 62 Fed Reg 8961; Feb 27, 1997); under the GGPs, certain new FDA guidance will include the opportunity for public comment before such guidance becomes effective.)*

Under FDA's ["automatic] detention[*"*] *without physical examination procedure* [system], products *may be detained without FDA examination or sampling. FDA communicates guidance on a particular product(s) to its Field offices through Import Alerts.* [are placed on automatic detention by the publication of Import Alerts]. *Id.* at 364-366. Products *that are the subject of an Import Alert* may be [described as the article itself, as having been,] *a general category of product or products* manufactured or distributed by particular entities, or [as] *products* originating from a particular country *or region of a country*. If a product is *the* subject [to] *of an* Import Alert, *FDA may detain* the *product without examination until* [it is not admitted until] the importer can demonstrate to FDA's satisfaction that the product is not adulterated or misbranded. *Id.* at 350-353. [With respect to food imports, and especially perishable food, automatic detention effectively halts shipments of adulterated and misbranded food. Importers are reluctant to take the risk of shipping product in the hope that, upon arrival, the product could pass inspection.] *FDA COMMENT: It has been FDA's experience that listing products as DWPE does not necessarily halt the presentation of shipments of these type products for importation.*

FDA has exercised its authority to refuse admission [to] *of* regulated products based on information, other than the results of examination of samples, that causes a product to appear to violate the FFDCA. *(This FDA action is based upon the "or otherwise" provision in section 801(a).)* For example, last year FDA placed all raspberries from Guatemala, regardless of grower, shipped during a particular growing season on *detention without physical examination because* [Import Alert. The basis for this Import Alert was that] traceback investigations *showed* [indicated] that these products "appear[] to have been manufactured, processed, or packed under insanitary conditions." Import Alert 20-40 (Rev. Mar.19, 1998). *(A food that has been prepared packed, or held under insanitary conditions whereby it may have been rendered injurious to health is deemed adulterated under section 402(a) of the FFDCA.)*

FDA has further asserted that [automatic] detention *without physical examination* may be imposed on future shipments of products if there is information *indicating* that [would cause] future shipments to appear to be in violation of the FFDCA. FDA Regulatory Procedures Manual (RPM) Chap. 9 at 347 (Aug.1995). For example, FDA may determine that [automatic] detention *without physical examination* would be appropriate if information indicates that the food was harvested from polluted waters, or that a product was manufactured

or held under insanitary conditions or in a manner that does not comply with FDA's good manufacturing practice requirements. *Id.* In particular cases, the courts have upheld FDA's authority to refuse admission to products based upon the appearance of adulteration or misbranding, and have held that such authority is committed to agency discretion.

II. U.S. DEPARTMENT OF AGRICULTURE REQUIREMENTS FOR THE IMPORTATION OF MEAT AND POULTRY INTO THE U.S.

A. USDA Statutory Authority to Regulate the Importation of Foods Into the U.S.

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) provide that products offered for import into the United States may not be adulterated or misbranded and must comply with all of the inspectional and other provisions of the Act and implementing regulations applicable to domestically produced products. 21 U.S.C. § 620 (FMIA); 21 U.S.C. § 466 PPIA). Once entry is authorized, the products are treated as domestic products, and are therefore subject to the same laws and regulations. *Id.* Products not in compliance may be destroyed unless they are exported by the consignee. 21 U.S.C. § 620(1,) (FMIA); 21 U.S.C. § 466(b) (PPIA). If an imported product does not comply with the FMIA because of misbranding, products may be brought into compliance, but only under USDA supervision. 21 U.S.C. § 620 (b).

Under the FMIA, USDA must report annually to the House of Representatives' Committee on Agriculture and the Senate's Committee on Agriculture, Nutrition, and Forestry regarding the certification of foreign plants that export to the United States. These annual reports concern issues such as inspection, sanitary, quality, species verification, and residue standards, and the equivalence of the standards in foreign plants to those governing domestically produced products. 21 U.S.C. § 620(e) - (f). These standards may be enforced through random inspections for species verification and for residues, and through random sampling and testing at the point of slaughter. 21 U.S.C. § 620(f). The Department also must provide the names and locations of plants authorized or permitted to export products to the United States, the number of officials employed by USDA assigned to inspect those plants, and the number of officials licensed from each country to inspect those products, as well as the total volume of products imported into the United States pursuant to this section. 21 U.S.C. § 620(e).

Under the PPIA, products offered for import into the United States are subject to the same inspection, sanitary, quality, species verification, and residue standards applied to domestic products, and the products must be processed in facilities and under conditions that are the same as required for domestic poultry products. 21 U.S.C. 466 (d). The Department also reports annually to the House Committee on Agriculture and the Senate Committee on Agriculture, Nutrition, and Forestry with respect to the slaughter of poultry, domestic and foreign, and the preparation, storage, handling, and distribution of poultry parts, and the inspection of poultry establishments. 21 U.S.C. § 470.

B. USDA Implementation of Its Statutory Authority

USDA has implemented its statutory authority governing meat and poultry products through a two-step certification system.

1. Exporting Country and Establishment Certification

USDA has delegated its authority to regulate imports to the Food Safety and Inspection Service (FSIS). 7 C.F.R. 2.3, 2.18. Before a firm may import a foreign meat or poultry product into the U.S., it must complete a two-step certification process. *First*, the exporting *country (e.g.*, Denmark) must be certified by FSIS as administering a meat or poultry inspection program equivalent to that of the U.S.' *Second*, the exporting country must certify the *manufacturing establishment* as complying with applicable U.S.-equivalent standards. 9 C.F.R. §§ 327.2 (Attachment F), 381.196 (Attachment F).

FSIS' Office of Policy Program Development and Evaluation (OPPDE) handles the requests of foreign countries for certification permitting exports to the U.S. OPPDE has certified 43 countries as exporting countries for products consisting of, or containing, cattle, swine, sheep, or goats. 9 C.F.R. § 327.2(1,). Five countries are certified to export poultry products into the U.S. 9 C.F.R. § 381.196(a)(4).

2. Other Relevant Requirements

We note the following additional requirements affecting meat and poultry products offered for import into the U.S.:

- Companies desiring to import meat/poultry products must apply for FSIS inspection of the products upon their presentation for entry into the U.S. 9 C.F.R. §§ 327.5, 381.198.

- All products offered for import must be accompanied by a foreign meat or poultry inspection certificate, bearing the official seal of the national government agency responsible for inspection and signed by an authorized official. Each foreign inspection certificate must be in both English and the language of the product's country of origin. 9 C.F.R. §§ 327.4, 381.197.

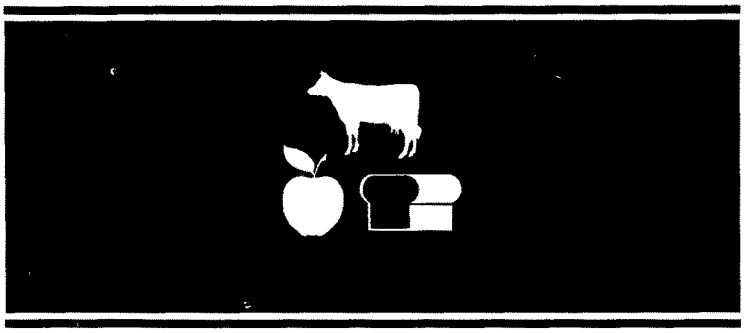
The meat and poultry inspection system in the U.S. is currently transforming from a "continuous inspection" system to the use of Hazard Analysis/Critical Control Point (HACCP) systems for food safety control. As USDA implements HACCP, equivalency determinations as to the inspectional system will be made with an eye towards whether the exporting country's regulatory system is equivalent to the U.S. HACCP-based regulatory model.

- Products offered for import must be reinspected by an FSIS inspector before they will be admitted into the United States. This inspection must take place at a U.S. processing establishment under FSIS inspection or an official import inspection establishment approved by FSIS. Every lot of product must be visually inspected for appearance and condition, and checked for certification and label compliance. Moreover, if deemed necessary, the inspector may take samples of product for laboratory analysis. No product may be moved from a processing/inspection establishment prior to reinspection. 9 C.F.R. §§ 327.6, 381.199.

Senate Permanent Subcommittee
On Investigations
EXHIBIT #5

FOOD SAFETY FROM FARM TO TABLE

A National Food-Safety Initiative



A Report to the President
May 1997

FOOD SAFETY FROM FARM TO TABLE:
A NATIONAL FOOD-SAFETY INITIATIVE

REPORT TO THE PRESIDENT
MAY 1997

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EXECUTIVE SUMMARY

While the American food supply is among the safest in the world, there are still millions of Americans stricken by illness every year caused by the food they consume, and some 9,000 a year--mostly the very young and elderly--die as a result. The threats are numerous and varied, ranging from *Escherichia coli* (*E. coli*) O157:H7 in meat and apple juice, to *Salmonella* in eggs and on vegetables, to *Cyclospora* on fruit, to *Cryptosporidium* in drinking water--and most recently, to hepatitis A virus in frozen strawberries.

In his January 25, 1997 radio address, President Clinton announced he would request $43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, increase seafood safety inspections, and expand food-safety research, training, and education. The President also directed three Cabinet members--the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency--to identify specific steps to improve the safety of the food supply. He directed them to consult with consumers, producers, industry, states, universities, and the public, and to report back to him in 90 days. This report responds to the President's request and outlines a comprehensive new initiative to improve the safety of the nation's food supply.

The goal of this initiative is to further reduce the incidence of foodborne illness to the greatest extent feasible. The recommendations presented in this report are based on the public-health principles that the public and private sectors should identify and take preventive measures to reduce risk of illness, should focus our efforts on hazards that present the greatest risk, and should make the best use of public and private resources. The initiative also seeks to further collaboration between public and private organizations and to improve coordination within the government as we work toward our common goal of improving the safety of the nation's food supply.

Six agencies in the federal government have primary responsibility for food safety: two agencies under the Department of Health and Human Services (HHS)--the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC); three agencies under the Department of Agriculture (USDA)--the Food Safety and Inspection Service (FSIS), the Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES); and the Environmental Protection Agency (EPA). Over the last 90 days, these agencies have worked with the many constituencies interested in food safety to identify the greatest public-health risks and design strategies to reduce these risks. USDA, FDA, CDC, and EPA have worked to build consensus and to identify opportunities to better use their collective resources and expertise, and to strengthen partnerships with private organizations. As directed by the President, the agencies have explored ways to strengthen systems of coordination, surveillance, inspections, research, risk assessment, and education.

This report presents the results of that consultative process. It outlines steps USDA, HHS, and EPA will take this year to reduce foodborne illness, and spells out in greater detail how agencies

will use the $43.2 million in new funds requested for fiscal year 1998. It also identifies issues the agencies plan to consider further through a public planning process.

The actions in this report build on previous Administration steps to modernize our food-safety programs and respond to emerging challenges. As part of the Vice President's National Performance Review (NPR), the agencies have encouraged the widespread adoption of preventive controls. Specifically, the NPR report urged implementation of Hazard Analysis and Critical Control Point (HACCP) systems to ensure food manufacturers identify points where contamination is likely to occur and implement process controls to prevent it. Under HACCP-based regulatory programs there is a clear delineation of responsibilities between industry and regulatory agencies: Industry has the primary responsibility for the safety of the food it produces and distributes; the government's principle role is to verify that industry is carrying out its responsibility, and to initiate appropriate regulatory action if necessary.

The Administration has put in place science-based HACCP regulatory programs for seafood, meat, and poultry. In late 1995, the Administration issued new rules to ensure seafood safety. In July 1996, President Clinton announced new regulations to modernize the nation's meat and poultry inspection system. The Early-Warning System the President announced in January will gather critical scientific data to further improve these prevention systems. Additional actions outlined in this report will encourage the use of HACCP principles throughout the food industry.

The need for further action is clear. Our understanding of many pathogens and how they contaminate food is limited; for some contaminants, we do not know how much must be present in food for there to be a risk of illness; for others, we do not have the ability to detect their presence in foods. The public-health system in this country has had a limited ability to identify and track the causes of foodborne illness; and federal, state, and local food-safety agencies need to improve coordination for more efficient and effective response to outbreaks of illness. Resource constraints increasingly limit the ability of federal and state agencies to inspect food processing facilities (e.g., years can go by before some plants receive a federal inspection.) Increasing quantities of imported foods flow into this country daily with limited scrutiny. Some food processors, restauranteurs, food-service workers, supermarket managers, and consumers are unaware of how to protect food from the threat of foodborne contaminants. These and other deficiencies will be addressed by key Administration actions outlined in this report and described below.

Enhance Surveillance and Build an Early-Warning System
As the President announced in January, the Administration will build a new national early-warning system to help detect and respond to outbreaks of foodborne illness earlier, and to give us the data we need to prevent future outbreaks. For example, with FY98 funds, the Administration will:

> **Enhance Surveillance**. The Administration will expand from five to eight the number of FoodNet active surveillance sentinel sites. Personnel at these sentinel sites actively look for foodborne diseases. Existing sites are in Oregon, Northern California, Minnesota,

Connecticut, and metropolitan Atlanta. New sites will be in New York and in Maryland, with an eighth site to be identified. CDC will also increase surveillance activities for certain specific diseases. For example, CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to food contamination, FDA will strengthen surveillance for *Vibrio* in Gulf Coast oysters, and CDC will strengthen surveillance for *Vibrio* in people.

Equip FoodNet sites and other state health departments with state-of-the-art technology, including DNA fingerprinting, to identify the source of infectious agents and with additional epidemiologists and food-safety scientists to trace outbreaks to their source.

Create a national electronic network for rapid fingerprint comparison. CDC will equip the sentinel sites and other state health departments with DNA fingerprinting technology, and will link states together to allow the rapid sharing of information and to quickly determine whether outbreaks in different states have a common source.

Improve Responses to Foodborne Outbreaks

At the federal level, four agencies are charged with responding to outbreaks of foodborne and waterborne illness: CDC, FDA, FSIS, and EPA. States and many local governments with widely varying expertise and resources also share responsibility for outbreak response. The current system does not assure a well-coordinated, rapid response to interstate outbreaks. To ensure a rapid and appropriate response, with FY98 funds, agencies will:

Establish an intergovernmental Foodborne Outbreak Response Coordinating Group Federal agencies will form an intergovernmental group, the Foodborne Outbreak Response Coordinating Group, to improve the approach to interstate outbreaks of foodborne illness. This group will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. It will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

Strengthen the infrastructure for surveillance and coordination at state health departments. CDC, EPA, FDA, and FSIS will assess and catalogue available state resources, provide financial and technical support for foodborne-disease-surveillance programs, and other assistance to better investigate foodborne-disease outbreaks.

Improve Risk Assessment

Risk assessment is the process of determining the likelihood that exposure to a hazard, such as a foodborne pathogen, will result in harm or disease. Risk-assessment methods help characterize the nature and size of risks to human health associated with foodborne hazards and assist regulators in making decisions about where in the food chain to allocate resources to control those hazards. To improve risk-assessment capabilities, with FY98 funds, the agencies will:

Establish an interagency risk assessment consortium to coordinate and guide overarching federal risk-assessment research related to food safety.

Develop better data and modeling techniques to assess exposure to microbial contaminants, and simulate microbial variability from farm to table. Such techniques will help scientists estimate, for example, how many bacteria are likely to be present on a food at the point that it is eaten (the end of the food chain), given an initial level of bacteria on that food as it entered the food chain.

Develop New Research Methods

Today, many pathogens in food or animal feed cannot be identified. Other pathogens have developed resistance to time-tested controls such as heat and refrigeration. With FY98 funds, the agencies will focus research immediately to:

Develop rapid, cost-effective tests for the presence in foods of pathogens such as *Salmonella*, *Cryptosporidium*, *E. coli* O157:H7, and hepatitis A virus in a variety of foods, especially foods already associated with foodborne illness.

Enhance understanding of how pathogens become resistant to food-preservation techniques and antibiotics.

Develop technologies for prevention and control of pathogens, such as by developing new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.

Improve Inspections and Compliance

With FY98 funds, the agencies will pursue several strategies to increase inspections for higher-risk foods; the agencies will, among other things:

Implement seafood HACCP. FDA will add seafood inspectors to implement new seafood HACCP regulations, and will work with the Commerce Department to integrate Commerce's voluntary seafood-inspection program with FDA's program.

Propose preventive measures for fresh fruit and vegetable juices. Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.

Propose preventive measures for egg products. Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

Identify preventive measures to address public-health problems associated with produce such as those recently associated with hepatitis A virus in frozen strawberries and *E. coli* O157:H7 on lettuce. These measures will be identified through a

comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

Improve coverage of imported foods. FDA will develop additional mutual recognition agreements (MRAs) with trading partners, initiate a federal-state communication system covering imported foods, and FDA and FSIS will provide technical assistance to countries whose products are implicated in a foodborne illness.

Further Food-Safety Education

Foodborne illness remains prevalent throughout the United States, in part because food preparers and handlers at each point of the food chain are not fully informed of risks and related safe-handling practices. Understanding and practicing proper food-safety techniques, such as thoroughly washing hands and cooking foods to proper temperatures, could significantly reduce foodborne illness. The Administration--working in partnership with the private sector--will use FY98 funds to, among other things:

Establish a Public-Private Partnership for Food-Safety Education. FDA, USDA, CDC, and the Department of Education will work with the food industry, consumer groups and the states to launch a food-safety public awareness and education campaign. The Partnership will develop, disseminate, and evaluate a single food-safety slogan and several standard messages. Industry has pledged $500,000 to date to support the partnership's activities and plans to raise additional funds.

Educate professionals and high-risk groups. Agencies will better educate physicians to diagnose and treat foodborne illness; strengthen efforts to educate producers, veterinarians, and state and local regulators about proper animal drug use and HACCP principles; and work with the Partnership to better train retail- and food-service workers in safe handling practices and to inform high-risk groups about how to avoid foodborne illness, e.g., in people with liver disease, illness that may be caused by consuming raw oysters containing *Vibrio vulnificus*.

Enhance federal-state inspection partnerships. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states) will be undertaken, in an important step towards ensuring the effectiveness of HACCP and ensuring that the highest-risk food plants are inspected at least once per year.

Continue the Long-Range Planning Process

Through this initiative, and through previous activities, HHS, USDA, and EPA have laid the groundwork for a strategic planning effort. There is a broad recognition of the need to carefully implement the initiative's programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort is needed to build on this common ground, and to tackle some of the difficult public-health, resource, and management questions facing federal

food-safety agencies. The federal food-safety agencies are committed to continuing to meet with stakeholders, ultimately to produce a strategic plan for improving the food-safety system.

A NEW INTERAGENCY STRATEGY TO PREVENT FOODBORNE DISEASE

In his radio message on January 25, 1997, President Clinton announced a new initiative to improve the safety of the nation's food supply. The President announced he would request $43.2 million in his 1998 budget to fund a nationwide early-warning system for foodborne illness, enhance seafood safety inspections, and expand food-safety research, risk assessment, training, and education (see Appendix A). President Clinton also directed the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to work with consumers, producers, industry, states, universities, and the public to identify additional ways to reduce the incidence of foodborne illness and to ensure our food supply is the safest in the world. The President directed Secretaries Glickman and Shalala and Administrator Browner to report to him with recommendations in 90 days. He instructed them to consult with a broad range of stakeholders in the food-safety system and to explore opportunities for public-private partnerships to improve food safety. And he asked that their recommendations include ways to improve surveillance, inspections, research, risk assessment, education, and coordination among local, state, and federal health authorities.

To start the discussion, the agencies issued a draft document summarizing their initial ideas. Subsequently, the agencies held two public meetings on March 5 and March 31-April 2, and established public dockets for written comments.

This report is the result of that 90-day process of deliberation and discussion among all stakeholders in the nation's food-safety system, including federal, state, and local agencies, consumers, academia, food producers, processors, manufacturers, distributors, representatives of the retail and restaurant sectors, veterinarians and health professionals, and many others.

The goal of this initiative is to reduce the incidence of foodborne illness to the extent possible. The recommendations presented in this report are based on the public-health principles that society should identify and take preventive measures to reduce the risk of illness and that it should focus its efforts on hazards that present the greatest risks.

FOODBORNE ILLNESS: A SIGNIFICANT PUBLIC-HEALTH PROBLEM

The Council for Agricultural Science and Technology, a private nonprofit organization, estimated in its 1994 report, *Foodborne Pathogens: Risks and Consequences*, that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. The Department of Agriculture (USDA) estimates that medical costs and productivity losses for 7 specific pathogens in food have been estimated to range between $6.5 billion and $34.9 billion annually. Total costs

for all foodborne illnesses are likely to be much higher. Those estimates do not include the total burden placed on society by the chronic illness caused by some foodborne pathogens.

Several population groups have increased susceptibility to foodborne infections, such as persons with lowered immunity due to HIV/AIDS and those on medications for cancer treatment or for organ transplantation, as well as pregnant women and their fetuses, young children, and the elderly. Patients taking antibiotics or antacids are also at greater risk of infection from some pathogens. The consequences of foodborne disease are particularly serious for those with inadequate access to health care, such as homeless people, migrant farm workers, and others of low socioeconomic status.

Sources of Foodborne Contamination

Bacteria and other infectious organisms are pervasive in the environment.

- *Salmonella* serotype Enteritidis enters eggs directly from the hen.
- Bacteria (occasionally pathogenic) inhabit the surfaces of fruits and vegetables.
- Molds and their toxic byproducts can develop in grains during unusually wet or dry growing seasons, damage and stress during harvesting, or during improper storage.
- Seafood can become contaminated from agricultural animal manures and wastes and other runoff, as well as by sewage, microorganisms, and toxins present in marine environments.
- Many organisms that cause foodborne illness in humans can be part of the normal flora of the gastrointestinal tract of food-producing animals without any adverse effects to the animals.
- Milk, eggs, seafood, poultry, and meat can become contaminated from contaminated feed, misuse of veterinary drugs, or poor farming practices, in particular, mismanagement of animal manures, including production and harvesting activities.
- Foods can become contaminated during processing due to malfunctioning or improperly sanitized equipment, misuse of cleaning materials, rodent and insect infestations, and improper storage.
- Foods can become contaminated in retail facilities and in homes through poor food-handling practices.

Some microbial pathogens give rise to diseases that are far more serious than the uncomfortable but relatively temporary inconvenience of diarrhea and vomiting, which are the most common symptoms of so-called "food poisoning." Foodborne infections can result in very serious immediate consequences, such as spontaneous abortion, as well as long-lasting conditions, such as reactive arthritis, Guillain-Barré syndrome (the most common cause of acute paralysis in adults and children), and hemolytic uremic syndrome (HUS), which can lead to kidney failure and death, particularly in young children. Some of the microbial pathogens that have been the source of foodborne illness cases and outbreaks recently include, *Salmonella*, *Campylobacter*, Shiga-like toxin-producing *Escherichia coli*, *Vibrio*, *Toxoplasma gondii*, *Cryptosporidium parvum*, Norwalk virus, and hepatitis A. A full description of these pathogens, the foodborne illnesses they cause, and frequently implicated foods may be found in Appendix B. In addition to microbial pathogens, other substances may contaminate foods and cause foodborne illness. Among these are naturally occurring mycotoxins and marine toxins.

THE CURRENT SYSTEM FOR PROTECTING FOOD

Our food-safety system, although generally successful in protecting the public, is characterized by complexity and diversity. Regulatory authority is divided among federal, state, and local governments. The private sector has the primary responsibility for ensuring the safety of the food that it produces. From the farm to the consumer's dinner table, the responsibilities can be summarized as follows:

- Consumer education on food handling and storage in the home is the primary responsibility of USDA's Cooperative State Research, Education, and Extension Service (CSREES), FSIS, FDA, and CDC. FSIS, with responsibility for meat, poultry and most egg products, FDA, with jurisdiction over all other foods, and CDC, with epidemiological capabilities, all produce educational materials. FDA and FSIS staff consumer hotlines, and all agencies have web sites. CSREES has an enormous network of extension agents across the country, and FDA has Public Affairs Specialists in offices around the country to respond to inquiries and conduct safe handling programs for consumers, health professionals, and the media.

- In the home, consumers have a responsibility for proper handling and storage of food. Because consumer use of proper food-handling practices can prevent many cases of foodborne illness, FSIS issued rules requiring the use of a safe-handling label on raw meat and poultry products.

- On the farm, food is regulated by state agencies supported principally by the Environmental Protection Agency (EPA), which acts to ensure that pesticides are approved for safe use; by the FDA, which oversees use of drugs and feed in milk- and food-producing animals; and by USDA's Animal and Plant Health Inspection Service (APHIS), which is concerned with food-animal-disease control. Federal responsibility also covers production and harvesting activities that discharge wastewater to surface and to

ground waters and solid waste to land, all of which could contaminate growing and processing waters or grazing land. Animal manures are currently excluded from the definition of solid waste under EPA's solid-waste-disposal regulation, and therefore, an EPA regulatory mechanism does not exist for these materials. The ecology of human pathogens in food animals and in their manures produced on farms and ranches, in slaughter operations, and in processing facilities has received little attention in the past. Regulations under the Clean Water Act require large animal-feeding operations to obtain a discharge permit.

- Food processing for foods other than meat, poultry, and egg products (except shell eggs) is regulated by FDA, whose inspectors are responsible for visiting about 53,000 plants periodically, with emphasis on the highest risk foods or processing techniques. FDA devotes about 700 inspectors and laboratory personnel to this activity. Meat, poultry, and all other egg products are regulated by FSIS, whose inspectors are present in slaughter and processing establishments to ensure that these products are safe, wholesome, and properly labeled. State and local governments also inspect food processors, with varying frequencies and under varying standards.

- Food being transported in interstate commerce is subject to federal and state regulation. In 1996, FSIS and FDA jointly published an Advanced Notice of Proposed Rulemaking (ANPR) on whether regulations are needed to govern the handling of meat, poultry, seafood, eggs, and other foods susceptible to microbial contamination during transportation. FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

- Importation of food from foreign countries is overseen by FSIS for meat, poultry, and most egg products and by FDA for all other foods. If an imported food is suspect, it can be tested for contamination and its entry into the United States denied.

- Restaurants, supermarkets, and institutional food services (such as schools and hospitals) fall under the FDA's retail food-protection program, a cooperative federal-state food-safety effort operated under the Public Health Service Act. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over retail establishments because the food used in these establishments traveled in interstate commerce, however, the PHS Act provides the means for more efficient regulation and use of available resources, as well as broader inspection coverage. FDA publishes the Food Code, which consists of model recommendations that states and local authorities adopt and use to regulate retail food establishments. FDA, along with FSIS and CDC, work with states biennially to update the Food Code.

- National standards for drinking water and criteria for surface waters are set by EPA and enforced generally by local public-water authorities; FDA establishes complementary standards for bottled water.

- Surveillance of foodborne illness is primarily the responsibility of state and local health departments and the CDC, which seek to identify cases of illness, determine their sources, and control outbreaks. CDC conducts field investigations of foodborne diseases only at the request of state health departments, which have the authority to implement outbreak control measures. FDA, FSIS, or both are called in when food within their jurisdiction is suspected. FDA and FSIS are charged with ensuring that foods implicated in a foodborne illness outbreak and traveling in interstate commerce are removed from the market.

- Research serves many purposes in reducing the incidence of foodborne illness and is integral to the programs of all public-health agencies. Research is essential to evaluate effectiveness of surveillance initiatives, control and prevention strategies, conduct risk assessments, and verify effectiveness of preventive techniques such as HACCP. Research into the cause and transmission of foodborne illness is the primary responsibility of CDC, FDA, ARS, CSREES, and EPA. The development of screening and analytic methods to rapidly and accurately identify and characterize foodborne hazards, identifying and tracking to the source the causes of foodborne illness, is the responsibility of FDA, ARS, CSREES, EPA, and CDC. Research to develop preventive technologies, ranging from new production techniques, to disinfection and food-processing techniques to reduce levels of pathogens, is the primary responsibility of ARS, CSREES, FDA, and industry. Basic research is conducted largely in university laboratories on the biology, genetics, pathogenesis, natural history, and epidemiology of microorganisms implicated in foodborne disease and is actively supported by the NIH, and in particular, by the National Institute of Allergy and Infectious Diseases. These efforts are focused on understanding the disease process and designing prevention and treatment strategies. Other agencies of the federal government also support related research in universities. The private sector supports research within its own laboratories and in universities.

THE FOOD-SAFETY SYSTEM MUST BE PREPARED FOR THE 21st CENTURY

The system for identifying and preventing foodborne illnesses described above was largely created in the early 1900s. It must be modernized. The system cannot properly identify, track, and control food-related illness, or prevent, to the extent possible, future cases from occurring. In 1981, FDA inspected food firms every 2-3 years, but can now visit those firms, on average, only once every 10 years (although some plants that produce higher-risk foods may be inspected more frequently). State and federal resources are not closely coordinated. Our understanding of some disease-causing organisms is so limited that our ability to protect the public health is seriously constrained.

The Clinton Administration has already taken a number of steps to improve the safety of the food supply.

- In 1993, the Vice President's National Performance Review issued a report recommending that the government and industry should move toward a system of preventive controls.

- FSIS and FDA issued regulations that will require the meat, poultry, and seafood industries to follow HACCP procedures. These HACCP rules require food industries to design and implement preventive measures and increase the industries' responsibility for and control of their safety-assurance actions. FSIS and FDA will streamline their current regulations as part of their conversion to HACCP.

- In 1994, CDC embarked upon a strategic program to detect, prevent, and control emerging infectious disease threats, some of which are foodborne, and has made significant progress toward this goal in each successive year.

- The Food Quality Protection Act of 1996, including many provisions of the Administration's bill, streamlined regulation of pesticides by FDA and EPA and put important new public-health protections in place, especially for children.

- Last year, the President signed the Safe Drinking Water Act of 1996, which includes regulatory improvements to help states and water-utility managers prevent drinking-water contamination problems. Resources are provided for the first time for drinking-water infrastructure that will help hundreds of communities protect their residents from harmful contaminants.

These advances are significant, but they are not enough. New pathogens, new food products, huge increases in imported foods, the growing importance of food exports, and increasing antimicrobial resistance among foodborne pathogens present new challenges to the nation's food-safety programs. The food-safety system is in need of change, especially change that builds on the preventive principles embodied in HACCP.

IMMEDIATE ACTIONS TO IMPROVE FOOD SAFETY

Because there are many causes of foodborne illness, many points at which foods can become contaminated, and many factors that make some groups of people more susceptible than others, no single preventive measure will ensure the safety of all foods. However, practical preventive steps can be taken immediately to reduce the incidence of foodborne infections.

The Administration's food-safety efforts focus on the hazards and foods that present the greatest risks to public health and impose the greatest economic burden on the nation, emphasize development and implementation of preventive controls of those risks, and seek to ensure that preventive controls are cost-effective. The Administration is emphasizing the use of HACCP

principles, and seeks opportunities for such controls through a collaborative process with the responsible sectors of the food industry and all other stakeholders.

Under this initiative, the federal government, in concert with state and local governments, industry and academia, would conduct research and risk assessments and cost-benefit analyses to determine how foodborne illnesses occur and can be prevented or controlled in the most efficient and cost-effective manner; improve surveillance and investigative efforts to locate and monitor illnesses caused by food; achieve more effective and efficient monitoring of the safety of the food supply through inspections of food processors; and reinvigorate education of all those involved in food preparation focusing on the use of safe practices. These issues, and actions and recommendations for addressing them are described below. Because the components of the food-safety initiative are interrelated, overlapping activities will be noted throughout this report (for example, among research and risk assessment, and education and inspection).

A NEW EARLY-WARNING SYSTEM FOR FOODBORNE DISEASE SURVEILLANCE

Background

The primary objective of the American system of public health is to prevent disease before it occurs. Although prevention of all disease might not be possible, stopping outbreaks of foodborne illness before they affect large numbers of people is a major goal. America needs an effective early-warning system that can detect and stop outbreaks before they spread. Such a system will also advance understanding of foodborne illness and further prevention efforts. In his January 25 radio address, the President announced a new national early-warning system for foodborne illness for which he is requesting funds in his FY98 budget.

Problem

The current public-health system in the United States has limited means to identify and track the causes of foodborne illness. A more effective early-warning system is needed to detect and stop outbreaks early before they spread. Also, the national and global increase in antimicrobial resistance is a compelling public-health problem. Human infections caused by resistant pathogens increase morbidity and mortality and increase health care costs as newer, more expensive antibiotics are needed to treat common infections.

Recommendations

Surveillance and investigation are powerful tools to detect new foodborne disease challenges, to determine what specific food sources are implicated in foodborne illness, and to learn how best to keep foods from becoming contaminated in the first place. Surveillance for antimicrobial resistance will allow early detection of resistance and containment of its spread. Rapid detection of outbreaks is critical to stopping them before they affect many people. A key element in an early-warning system is the ability to detect, compare, and communicate unusual patterns of illness and laboratory findings within and among states and federal partners.

Enhancing the capacity of states to monitor foodborne disease and to investigate and control outbreaks will lead to better general control measures and fewer illnesses. One way to achieve this is to enhance and expand the existing Foodborne Disease Active Surveillance Network (FoodNet) to identify, investigate, and control a broad spectrum of foodborne diseases. A second important way to enhance early warning is to increase the capacity of many states to deal with new foodborne challenges. These enhancements will help us identify outbreaks and other foodborne disease challenges early, and prevent illness and premature deaths related to foodborne diseases.

In cooperation with state and local health departments, the federal government is proposing to take the following steps to establish a national early-warning system for foodborne diseases, and to enhance surveillance of such disease. These changes will result in an improved system for promptly and accurately detecting and reporting foodborne illnesses and outbreaks so public-health agencies can rapidly institute appropriately and correctly focused measures to control the spread of foodborne disease. This system will also collect critical data to recognize trends and target prevention strategies, including systems based on HACCP principles, and to evaluate the effectiveness and efficiency of prevention strategies already in place.

Enhance and Expand Foodborne Disease Active Surveillance

CDC, FDA, and FSIS support five FoodNet sites at state health departments to track cases of foodborne infections and to determine the sources of the most common ones. The existing sites will be strengthened, and their number increased to seven in FY97, and to at least eight in the following year. The sites and federal food-safety agencies will be electronically linked to create a powerful new network to detect, respond to, and prevent outbreaks of foodborne illness. Adding additional sites will improve geographic and demographic representation, making this network more likely to detect diseases and outbreaks that are regional rather than national in distribution.

FY97 Activities

- Two new active surveillance sites, in New York and Maryland, will begin FoodNet activities.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, FSIS, and the Council of State and Territorial Epidemiologists (CSTE) will add at least one site to FoodNet, and CDC will enhance personnel resources at all sites to improve surveillance, analysis of data, and timely and appropriate release of information.

- CDC and the FoodNet sites will develop and conduct case-control studies of *Campylobacter* and *Cryptosporidium* infections to guide control efforts.

Enhance Early Detection of Foodborne Disease Nationwide

The early-warning system will enhance improved early detection of foodborne disease in additional states in FY98 by providing resources for improved surveillance, investigation, control, and prevention of foodborne disease outbreaks. Although sophisticated laboratory studies can identify causes of illness and show relationships among pathogens, laboratory methods are insufficient without investigators who can collect samples, interview people, and trace the source of contamination to find out why the illness occurred. New electronic tools need to be developed to enable rapid detection of outbreaks and to enhance communication about outbreaks to appropriate agencies. CDC also should provide additional resources to states to increase their

surveillance and response capacity for the serious long-term consequences of foodborne disease, such as hemolytic uremic syndrome (HUS).

FY97 Activities

- CSTE and CDC, in conjunction with FDA and FSIS, will develop a protocol for evaluating epidemiologic outbreak data. The group will also develop criteria for local and state health officials to provide information on outbreaks to federal authorities for review and necessary action.

- FoodNet sites will gather epidemiologic data on cases of HUS.

FY98 Activities with Food-Safety Initiative Funds

- CSTE and CDC, in conjunction with FDA and FSIS, will define critical capacity elements that state and local health departments require to conduct surveillance, investigation, control, and prevention of foodborne illnesses; CDC will help states remedy identified deficiencies.

- CDC and CSTE will develop an electronic module for collecting and transmitting data to CDC on outbreaks of foodborne illness.

- CDC will begin a case-control study of hepatitis A to determine the proportion of cases due to contamination of food so that optimal control strategies could be determined. Recognized foodborne outbreaks account for about 2 to 5% of annually reported hepatitis A cases and are usually caused by an infected food handler.

- Epidemic assistance for outbreaks of foodborne disease will be expanded when states request direct CDC participation in investigations.

- CDC and, where appropriate, FDA and FSIS, will collaborate with state health departments to improve diagnostics, outbreak detection, and electronic communications.

- *Vibrio* surveillance will be strengthened by CDC, FDA, and states by increasing personnel, epidemiologic, and laboratory resources devoted to the Gulf Coast *Vibrio* surveillance program.

Long-term Activities

- Surveillance and investigative systems should continue to be enhanced to improve the ability of state and local health departments to promptly and accurately identify foods that are the source of foodborne illness.

Modernize Public-Health Laboratories

CDC should provide resources and training to upgrade public-health laboratory capabilities in FoodNet sites and in states without those sites so the laboratories can rapidly identify a broad range of foodborne pathogens, including parasites and viruses, and can use new techniques like DNA fingerprinting. The new capacities would allow rapid identification of the cause of some outbreaks that currently go undiagnosed.

FY97 Activities

- CDC will collaborate with FoodNet sites to determine serotypes of *E. coli* other than O157:H7 that cause HUS in children.

FY98 Activities with Food-Safety Initiative Funds

- The Association of State and Territorial Public Health Laboratory Directors (ASTPHLD) and CDC will improve diagnostic assays and provide additional resources to improve the capacity of state laboratories to detect foodborne pathogens, including selected viruses and parasites.

- CDC will provide sufficient funds to states to support the production of serotyping reagents for *Salmonella*, which are critical for outbreak identification.

- CDC will develop DNA amplification-based tests for foodborne pathogenic bacteria that are difficult to detect by culture (e.g., Shiga-like toxin-producing *E. coli* other than *E. coli* O157:H7 and other disease-causing *E. coli*) and will provide resources and technical assistance to states to improve their capacity in diagnosing those pathogens.

Long-term Activities

- CDC should begin developing molecular alternatives to serotyping for *Salmonella*.

Create a National Electronic Network for Fingerprint Comparison

CDC should fund a new computer network and database system that would capture fingerprints of pathogens in a national database, linking CDC, FDA, FSIS, and states that have that new capacity into a national network. This technology would, for example, permit rapid recognition that an *E. coli* O157:H7 bacterium cultured from a patient in Washington was indistinguishable from one isolated from another patient in California. That might suggest to public-health investigators that a product distributed in California and Washington was contaminated with the same organism.

In addition to identifying, investigating, and reporting cases of foodborne disease in humans, microbiological surveillance of pathogens in foods, in food animals and their manures, and in animal feed, is important to control and prevent foodborne diseases and to evaluate the measures that reduce the risk of exposure. Therefore, to make the early-warning system fully operational and to translate its findings into long-term improvements in the safety of the food supply, additional surveillance activities would be required.

FY97 Activities

- CDC will provide resources and technical assistance to state health departments for DNA fingerprinting of *E. coli* O157:H7, and begin to establish a centralized national electronic database of DNA fingerprint patterns.

FY98 Activities with Food-Safety Initiative Funds

- The national electronic database of DNA fingerprint patterns of *E. coli* O157:H7 will continue to be expanded.

- In collaboration with participating state health department laboratories, FDA and FSIS, CDC will develop standardized methods for DNA fingerprinting of *Salmonella* serotypes Typhimurium and Enteritidis and will transfer the techniques to selected state health departments.

- CDC, ASTPHLD, and CSTE will develop guidelines for maximizing the utility of DNA fingerprinting at state health departments in foodborne disease surveillance and outbreak investigations.

- CDC, FDA, and FSIS will set up centralized national electronic databases of DNA fingerprint patterns of *S.* Typhimurium and Enteritidis.

Long-term Activities

- CDC should continue to develop standardized DNA fingerprinting methods for other foodborne disease-causing bacteria as appropriate and should transfer the standardized methods to state health departments and appropriate federal laboratories.

- CDC should begin implementing automated foodborne disease outbreak detection algorithms based on the DNA fingerprint patterns submitted by state health department laboratories.

Increase National Surveillance for Antimicrobial Resistance of Foodborne Pathogens

The problem of foodborne disease is increasing, in part, because foodborne infections are becoming more serious. One of the ways foodborne pathogens become more virulent is by acquiring resistance to antimicrobial agents, making such infections very difficult to treat. Therefore, CDC should expand surveillance for antimicrobial resistance in *Campylobacter*, *Salmonella*, and *E. coli* O157:H7 isolated in humans, and FDA and FSIS should take similar steps for those bacteria isolated from food-producing animals and their manures and from food products in a way that permits those data to be compared. CDC, FDA and FSIS should develop standard procedures for sharing information and for responding to increases in resistance or other "red-flag events" such as the discovery of an important new resistant bacterium.

FY97 Activities

- CDC, FDA, and FSIS will conduct surveillance of antimicrobially resistant *Salmonella* and *E. coli* O157:H7 isolates.

FY98 Activities with Food-Safety Initiative Funds

- CDC, FDA, and FSIS will initiate surveillance of antimicrobial resistance in isolates of *Campylobacter* from humans and animals, including poultry.

- FDA and CDC will conduct surveillance and epidemiologic studies to monitor and reduce the incidence of foodborne disease associated with emerging and drug-resistant pathogens.

Long-term Activities

- CDC, FDA, and FSIS should continue monitoring and comparing the antimicrobial resistance of *E. coli* O157:H7, *Salmonella*, and *Campylobacter* strains in humans and animals.

- FDA and CDC should conduct physician and veterinary drug-prescribing surveys, including patients and animal producers, to assess the effect of antimicrobial drug use on resistance patterns and prevalence to guide regulatory policy and educational campaigns.

- FDA should assist the World Health Organization (WHO) in the development of a veterinary database within the WHONET system. (WHONET is a system for standardized international reporting of antimicrobial resistance to WHO.)

Conduct Surveillance of Human Pathogens in Food-Animal Populations and Enhance Oversight of Animal Feedstuffs, Feeds, and Manures for the Effect of Drugs and Other Therapies

FY98 Activities with Food-Safety Initiative Funds

- USDA, CDC, FDA, and EPA will convene a working group to discuss how to conduct surveillance of human pathogens in food animals and their manures, and should target one pathogen on which to begin surveillance in FY99.

Long-term Activities

- FDA should increase the monitoring of animal-feed processing to determine the nature and extent of pathogen contamination and the effect of control strategies on pathogen reduction in animals.

INTERSTATE OUTBREAK CONTAINMENT AND RESPONSE COORDINATION

Background

Four federal agencies are charged with responding to outbreaks of foodborne illness (including waterborne illness): FDA and CDC (at HHS), USDA, and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility with the federal government for response to such outbreaks. When an outbreak occurs, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. FDA, FSIS, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes (other than animal manures) that have the potential to contaminate the air, land, or waters used to produce the food product. The type of food affected determines which regulatory agency has primary jurisdiction: FSIS regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has clearly defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments also have a critical role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents. Although foodborne outbreaks are sometimes local, most outbreaks implicate federal agency jurisdiction. Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners. Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products. In some instances, on-site assistance is requested by the local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem. For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

Companies responsible for affected products also have a critical role to play. Food companies are sometimes the first to recognize that their product is causing illness. In addition, food-product

recalls are voluntary, although FDA may request a company to recall products. Federal and state agencies can benefit from industry's expertise about food products and their distribution patterns.

Problem

Although significant coordination already occurs among federal, state, and local agencies, better coordination is needed to meet new and growing threats to the nation's food supply. More than one agency is involved in virtually every large foodborne outbreak. Joint efforts are often hindered by a lack of communication or a misunderstanding of each agency's role in a particular situation.

Recommendations

Federal, state, and local governments should improve the coordinated management of interstate outbreaks. Improved coordination among the federal agencies, among federal, state, and local agencies, among the various state agencies, and between state and local agencies would enhance the level of public health protection, leverage agency resources and experience, and avoid duplication of effort.

The early-warning capability, comprised of FoodNet and strengthened state-surveillance capacity, and improved federal-state communications will enhance appropriate involvement of federal agencies in the investigation of foodborne disease outbreaks. Communication and exchange of information among the appropriate federal, state, and local government agencies must be improved.

Improve Outbreak Containment Through Better Federal-State-Local Coordination of the Evaluation of and Response to Foodborne Illness

There are probably hundreds of times a year when at least one federal agency, working with state and local agencies, plays a role in detection, investigation, and containment of illnesses that may be caused by contamination of food. Occasionally (typically once or twice a year) the outbreak is sufficiently significant and complex to require the involvement of the highest level officials in the responsible federal agencies. When this occurs, it is essential that federal agencies speak with one voice.

A critical element of an effective, rapid response to a foodborne illness outbreak is ready communication by all the involved parties at the federal, state, and local level. Although there are communication systems in place, they need to be expanded and coordinated to achieve rapid exchange of information and data between key outbreak-response personnel in each agency at the federal, state, and local levels. This strengthened system will complement the data and information exchange systems described in the "Early Warning for Foodborne Disease Surveillance" section of this report.

As part of this initiative, the agencies have streamlined their outbreak-response procedures. The departments with a role in any foodborne illness outbreak will be determined by public-health responsibility and regulatory jurisdiction over the food products (or water) implicated in the outbreak. Each department with public-health responsibility and regulatory jurisdiction over food products (or water) implicated in an outbreak will designate a Coordinator responsible for that department's activities related to the outbreak.

This new management system will provide a common set of objectives and strategies and one spokesperson that will speak on behalf of the federal government. Once there are indications to federal or state agencies of a large-scale problem, the staff will tell the Coordinator who will then coordinate the response among federal and state agencies.

Each agency has specific mechanisms in place to aid in this effort. FSIS has established an Emergency Response Program to prevent and control foodborne disease outbreaks involving meat, poultry, and egg products. Likewise, FDA's Division of Emergency and Investigational Operations serves this function for all other food products. Both FDA and FSIS maintain 24-hour telephone service staffed with a duty officer trained to respond to emergencies and ongoing illnesses, including foodborne illness and outbreaks, who have access to emergency personnel throughout the agency, as well as with emergency contacts in other agencies. FDA's Division of Emergency and Investigational Operations will serve to coordinate with other agencies. CDC provides 24-hour emergency consultation for botulism and other foodborne disease clinical emergencies and stations Epidemic Intelligence Service officers in 15-20 states each year to support surveillance and emergency response at the state level.

In order to improve communications with state agencies, FDA has adopted a fax-on-demand and fax broadcast system. The fax broadcast system, containing a database of more than 900 state officials, permits messages to be sent any time of day or night to any list of state contacts, providing an early alert or update to foodborne illness investigations. The fax-on-demand system provides access to press releases from federal agencies, press releases from firms about their recall, as well as other information. FSIS communicates with state departments of health and coordinates outbreak response through CDC WONDER (Internet) and both FDA and USDA maintain liaisons at CDC to facilitate food-safety activities, including outbreak investigations. CDC has established rapid communication links with all state and territorial epidemiologists and public health laboratory directors providing rapid group electronic mail and group fax links, and conference calls in outbreak settings.

FDA has also instituted a 50-state conference call system to keep all state agencies up-to-date on major foodborne outbreaks. This system was first used for the outbreak involving *E. coli* O157:H7 in apple juice and was most recently used for the hepatitis A outbreak associated with frozen strawberries. FDA and CDC jointly participate in these calls to assure more effective follow up and control of outbreaks. FDA will modify the conference call system to involve appropriate states in the very early stages of any multistate outbreak, as well as continuing the 50-

state update conference calls, in order to ensure better communication among state and federal agencies.

FY97 Activities

- To further strengthen our outbreak-response systems, CDC, EPA, FDA, and FSIS will establish an intergovernmental group, the Foodborne Outbreak Response Coordinating Group (FORCG), to improve the approach to interstate outbreaks of foodborne illness. FORCG will provide for appropriate participation by representatives of state and local agencies charged with responding to outbreaks of foodborne illness. This group will also review ways to more effectively involve the appropriate state agencies when there is a foodborne outbreak.

- FORCG will review and evaluate outbreak response. FORCG will undertake these reviews after appropriate consultation with industry and consumer representatives. Based on these deliberations, FORCG will assess the infrastructure for outbreak response, make recommendations for improving the current system, and work with federal, state, and local governments, the food industry, health professionals, and consumer advocates to implement beneficial changes. FORCG will meet several times a year for this purpose.

- Under the new initiative there will be one person/position designated as the outbreak coordinator for each department or agency that has a role in the outbreak response. This position will be established as a formal institutional position, with appropriate backup designees. For outbreaks that fall within the purview of HHS, HHS will designate the Assistant Secretary for Health to be the primary person in charge of coordination for HHS. For outbreaks that fall within the purview of USDA, the Under Secretary for Food Safety will coordinate for USDA. EPA will designate the Assistant Administrator for Water as the primary person in charge of coordination for EPA when drinking water is involved.

- Standard procedures will be developed for the rapid exchange of data and information associated with foodborne illness outbreaks between involved agencies and for dissemination to the public. The procedures will be developed by FORCG and representatives from the appropriate state agencies. The procedures will cover the exchange of data and information associated with an outbreak and will complement systems established for exchange of information about day-to-day occurrences of foodborne illness. (See "A New Early-Warning System for Foodborne Disease Surveillance" section.) The procedures will also provide for rapid dissemination of accurate information to the public by the agency spokesperson.

Enhance State and Local Infrastructure for Foodborne Outbreak Detection, Evaluation, and Response Coordination

The epidemiology offices and laboratories within state and local health departments are charged with the surveillance of infectious and non-infectious conditions, and, along with other state and local officials, with the investigation of outbreaks. They collect surveillance data from physicians, laboratories, local health departments, and other sources. Yet, the resources available in many states and communities for the surveillance and investigation of foodborne diseases are limited and decreasing, thereby limiting the effectiveness of their response. As a result, outbreaks may go undetected or are never investigated.

CDC, EPA, FDA, and FSIS will address the problem first by assessing and cataloguing available state resources, and then by working with states and providing support for foodborne-disease-surveillance programs and assistance to better investigate outbreaks of foodborne illness.

FY97 Activities

- FORCG, with assistance from the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the Association of State and Territorial Public Health Laboratory Directors, the Council of State and Territorial Epidemiologists, and the National Association of State Departments of Agriculture, will begin a nationwide audit to catalogue the existing state and local food-safety program infrastructure.

- FORCG, in consultation with the appropriate outside organizations, will establish working groups with appropriate participation of federal, state, and local officials to develop recommended procedures for outbreak-response coordination at the state and local level.

FY98 Activities with Food-Safety Initiative Funds

- CDC, EPA, FDA, and FSIS will assist states and local governments in developing the infrastructure necessary to ensure proper detection, evaluation, and coordinated response to foodborne outbreaks.

RISK ASSESSMENT

Background

The impact of increased funding for development of methods and models directed at improving risk assessments will be to focus public resources on reducing those risks that have the greatest consequences for human health. Risk assessment provides a strong foundation upon which efficient allocation of scarce food-safety resources can be made. While obvious severe hazards in the food supply will be addressed through the larger food-safety initiative, risk assessment provides an objective foundation upon which efficient allocation of scarce food-safety resources can be established. Furthermore, risk assessment often plays a central role in the development of any science-based system of preventive controls.

There has been a long history of performing safety assessments or risk assessments for foods, particularly chemicals and drug residues. Risk assessments, cost-benefit analyses, and evaluations of alternative risk-management strategies are required for all major regulations in USDA, a requirement imposed by the Federal Crop Insurance Reform and Reorganization Act of 1994 (P.L. 103-354). EPA is developing methods for required risk assessments under the Safe Drinking Water Amendments of 1996, including both microbial and chemical hazards. Sound risk assessments are important in various aspects of international trade, including the provisions of Codex Alimentarius and the World Trade Organization, the international bodies that govern standards for food safety, among other issues. Carefully formulated risk assessments based on high-quality data and scientific information generated from research lead to more informed risk management and better decisions.

Risk assessment also provides essential information for estimating and analyzing the costs and benefits of policy alternatives. Risk estimates are used to characterize the state of the world in the baseline and the alternative states expected to occur after taking action, whether through regulation, guidelines, or education campaigns. Ideally, results of risk estimates are in the form of distributions that capture the scientific uncertainty and population variability, but where that is not possible, point estimates of risk need to reflect the impact on the entire population.

Risk management and risk assessment must mutually inform each other but must remain separate and independent entities. Risk communication must be an integral part of all risk-related activities, including the public, industry, and all affected parties.

Good risk assessment requires good risk communication. Participation from industry, academia, and private risk organizations will be ensured in the interagency consortium's risk-assessment activities. Good risk communication must be ensured by interfacing with educators. Active communication between the risk assessment consortium and the research community is crucial to a successful initiative.

Risk assessment characterizes the nature and size of the risk to human health associated with hazards, and to make clear the degree of scientific certainty of the data and the assumptions used to develop the estimates. Risk assessments require specific information on the hazard and on the exposed population to provide meaningful information for those making risk-management decisions. Even for chemical hazards, for which risk-assessment methods have been most thoroughly developed, data gaps force the use of assumptions about exposure, hazard potency, and characteristics of the population at risk.

Problem

Risk assessment is far less developed for foodborne pathogens. Intensive commitment is necessary to develop critically needed methods of analyzing the available data and addressing its uncertainty; methods that account for variability, specifically of living microbial pathogens, are essential. Chemical and radiological risks do not pose these special challenges, so extending these established methods to microbial risk is not sufficient.

The research needed to develop improved methods and models that will make it possible to perform quantitative microbial risk assessments to the degree of complexity required for most food-safety issues will require the integration of work in biological sciences, predictive microbiology, and applied mathematics. In some instances, the research needs overlap with those identified in the research section of this document. However, to reflect the multidisciplinary nature of the needed research programs and to highlight the critical nature of the research needs, research needs related to risk assessment are being presented as a separate item for consideration.

Recommendations

This initiative emphasizes the development, testing, and validation of microbial risk assessment and foodborne illness valuation methods. These efforts should support effective and efficient public response to foodborne illness concerns, whether the response is improved surveillance plans, better prevention strategies, or stronger inspection models. The initiative's activities focus on developing models for improving risk assessment, thereby more precisely targeting the prevention of foodborne disease by informing surveillance plans, prevention strategies for process-control systems and for food inspections based on HACCP principles, and research programs to fill critical food-safety information gaps. Recommendations are being made in three areas.

Establish a Risk Assessment Consortium

All federal agencies with risk-management responsibilities for food safety will establish jointly a consortium at which federal agencies can collectively advance the science of microbial risk assessment, and to assist agencies in fulfilling their specific food-safety regulatory mandates. The consortium should be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, as well as industry and

consumer groups. The goal of the consortium would be to improve the quality of risk-assessment research by coordinating research priorities, eliminating redundancies of effort, and encouraging multidisciplinary research efforts. The consortium will have three primary functions:

- Develop a scheme for setting methodological research priorities based upon the value of information expected from each research activity.
- Serve as a clearinghouse for information about current and planned research projects pertinent to microbial risk-assessment techniques.
- Foster and, where possible, augment the research activities of the member agencies to accelerate particularly critical research projects.

FY97 Activities

- The consortium, which will include all interagency partners, will be established in 1997 as part of the Joint Institute for Food Safety and Applied Nutrition, a collaborative activity of FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine and the University of Maryland. The initial focus of the initiative will be on pathogenic microorganisms.
- The consortium will begin the process of establishing a clearinghouse that will collect and catalogue available methodology, specifically simulations necessary to address microbial growth and death variables offered by the private sector, trade associations, federal and state agencies, and international sources. The consortium will work with its member agencies to catalogue their microbial risk-assessment-research advances and identify data sets that would provide the scientific data needed to develop new models. The consortium will be inclusive in its risk-assessment activities, seeking expertise from risk-assessment professionals and scientists from public and private sources, and industry and consumer groups.

FY98 Activities with Food-Safety Initiative Funds

- A series of public meetings will be held to develop a strategy to address long-term research needs for the analysis of farm-to-table scenarios, including potential pathogen introduction at each level (e.g. farm, processing, transportation, home, restaurant, and retail food handling), food-consumption data, and computer modeling. A strategic plan will be developed for research into dose-response calculations, chronic sequelae, biomarkers, and adapting surveillance data. This process will include a broad spectrum of academic, industry and government expertise that will be obtained through an acceptable process such as an advisory committee.

- Begin a comprehensive review of existing data and federal information-collection programs to determine the extent to which they may fill existing data gaps, and suggest additional data needs to better support risk assessments.

Long-term Activities

- The consortium will continue to collectively identify critical research needs, propose effective research on analytical approaches and methods, and reach consensus on the priority of these needs based on their potential to reduce the uncertainty of risk-management decisions in food safety and provide the greatest positive impact. Research supported and conducted through this initiative would cover several areas critical to developing our ability to conduct risk assessments for foodborne disease-causing organisms and to assess the effectiveness of control measures.

Develop and Validate Exposure Assessment Models Based on Probabilistic Methodology

Risk assessment of foodborne illness is dependent on accurately estimating the probability that various quantities of a toxin or pathogen will be ingested by the consumer (i.e., exposure assessment). This initiative addresses numerous data and modeling deficiencies in estimating exposure to microbial and chemical contaminants. Specifically, research will be conducted into the development of models and simulations based on probabilistic methods for the occurrence of microbial pathogens and chemical hazards in food at all stages of the food chain; typical behaviors of commercial and home preparation operations; validation of dynamic exposure assessment models; evaluation of intake data regarding food-consumption patterns of the general population and sensitive subpopulations; and specific data on microbial behavior in food vehicles of sporadic and epidemic disease. Research on how to incorporate data related to biomarkers should be pursued. (Biomarkers are surrogates that indicate that exposure has occurred or that some effect has occurred, particularly when actual evidence of exposure or effect is difficult or impossible to obtain.)

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in two areas that are in need of augmentation: exposure assessment methods, and techniques for acquisition and analysis of experimental data for model development. Initial areas identified include:

- Addressing the dynamics of foodborne pathogens in agricultural environments (e.g. pathogen reservoirs, feed, and animal manure).

- Quantifying effects of key processing steps on levels of pathogens.

- Quantifying effects of key commercial food service preparation procedures, marketing facilities, and home food-handling practices.

- Designing and proposing ways to integrate the collection of exposure and dose-response data into outbreak investigation.

Long-term Activities

Future initiatives would be fluid to adjust to results of short-term research, emerging food-safety needs, and changes in the direction of research programs within individual agencies. Additional research would likely include the development of modeling techniques to assess human exposure resulting from the subtherapeutic use of veterinary antibiotics in food-producing animals. To reduce uncertainties in exposure estimates, the consortium will work with researchers who are conducting focused food-consumption surveys targeting foods consumed by a variety of subpopulations (e.g., the elderly, children).

Develop and Validate Dose-Response-Assessment Models for Use in Risk Assessment

Research is needed to accurately estimate the relationship between the quantity of a biological agent and the frequency and magnitude of adverse human health effects in a population. Dose-response assessments typically include estimates of the rates of infection, morbidity, and mortality.

FY98 Activities with Food-Safety Initiative Funds

Working with FDA, EPA, and USDA, the consortium will identify priority research programs in dose-response-assessment methods and models that need to be augmented. Initial areas identified include:

- Methodology to incorporate the use of biomarkers in exposed populations into risk-assessment models.

- Identification and development of criteria for objective models that permit high-to-low-dose extrapolation.

- Development of criteria that will be used to select or weight alternative models (theories) for extrapolating from empirical data to quantitative descriptions of risk.

Long-term Activities

Risk-assessment research priorities in this area will be collectively established by the interagency consortium. Additional research includes studying whether threshold or non-threshold models for infectivity are more appropriate for describing low-dose infectivity rates for infectious and toxicoinfectious microorganisms. Further research is also needed into the use of biomarkers of susceptibility, chronic sequelae, microbiological toxicokinetics, and infectious dose.

RESEARCH

Background

Food-safety research is critically needed to develop the means to identify and characterize more rapidly and accurately foodborne hazards, to provide the tools for regulatory enforcement, and to develop effective interventions that can be used as appropriate to prevent hazards at each step from production to consumption. FDA, CDC, EPA, NIH, ARS, and CSREES, conduct research related to pathogenic microorganisms and other contaminants that threaten the safety of food. That research supports the needs of both the federal and state food-safety agencies and the many food industries.

Problem

New foodborne pathogens have emerged over the past ten years. Other microorganisms, previously thought to be innocuous, have been linked to life-threatening diseases after acquiring new virulence genes and antimicrobial resistance. Many of those organisms cannot be detected readily due to either a lack of suitable methods or their sporadic occurrence in foods. Certain foodborne pathogens are increasingly associated with resistance to time-tested controls, such as heating, refrigeration, and acid. In some cases, that ability appears to be linked with increased virulence or new ways to evade our immune defenses. The various research programs of FDA, ARS, CSREES, CDC, EPA, and NIH need to better coordinate their research efforts on the highest-priority issues and work together more effectively to leverage each other's resources.

Recommendations

Prevention of foodborne pathogens in foods requires an understanding of how foods become contaminated during their production, processing, and distribution, and the availability of practical interventions to control or eliminate the biologic agent. Selection of target pathogens and foods ideally are guided by risk assessment. Research is also needed to support HACCP implementation to verify that critical control points in HACCP systems are working, and to target the data gaps that hamper HACCP and risk assessment. Among the recognized data gaps, the following areas were identified as priority research needs. (Research activities listed for FY97 and FY98 are not necessarily completed in those years. Therefore, activities listed as long-term are additional activities.)

Improved Detection Methods

Many pathogens cannot be easily detected in foods, e.g., *Cyclospora* in raspberries. Among the needs for improved diagnostics, methods are needed for rapid, cost-effective testing for pathogens in food animals and their manures, in agriculture and aquaculture products, animal feeds, and processed food products. Methods development must address the low-level, sporadic incidence of many pathogens in foods. Research will be coordinated with EPA's efforts to develop better

test methods for *Cryptosporidium* and other pathogens in water and drinking water. Improved methods are needed for the identification and subtyping of foodborne pathogens in human and animal clinical specimens. The development of effective sampling plans and enrichment techniques are vital parts of detection methodology.

FY97 Activities

- EPA, CDC, ARS, CSREES, and FDA, in conjunction with states and academia, will conduct research to develop detection methods and control measures for *Cyclospora*.

FY98 Activities with Food-Safety Initiative Funds

- ARS, FDA, and EPA will enhance ongoing research to develop test methods for *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7 and other Shiga-like toxin-producing *E. coli*, *Cryptosporidium*, hepatitis A and Norwalk viruses, and naturally occurring mycotoxins and marine toxins in foods.

- FDA will expand its ongoing research on the development of methods for detecting foodborne pathogens in animal feeds.

Long-term Activities

- FDA, ARS, CSREES, and EPA should undertake research to develop test methods for *Vibrio vulnificus* in foods.

Understanding Resistance to Traditional Preservation Technologies

Microorganisms that are resistant to antimicrobial agents and processing techniques that have been relied on traditionally to eliminate or prevent the growth of foodborne pathogens have become increasingly important causes of serious foodborne disease. Research is needed to determine how microorganisms associated with foodborne disease become tolerant to various types of antimicrobials and to traditional food-safety safeguards, such as heat or cold, low pH, high salt, and disinfectants, and to elucidate factors in animal- and plant-production systems and processing environments that influence the development of resistance. The physiological and genetic bases of resistance are not understood well enough to prevent breakthrough of newly emerging pathogens. Such research will help identify food production, processing, and handling practices that are likely to contribute to pathogen contamination or proliferation. That research is also needed to guide improvement of traditional techniques and the development of new interventions.

Long-term Activities

- ARS, CSREES, and FDA should undertake research into physiological, genetic, and other factors that cause foodborne-disease-causing microorganisms to develop resistance to preservation technologies.

Understanding Antibiotic Drug Resistance

Pathogens in food-producing animals and their manures may become resistant to antibiotics and drugs, particularly when used improperly. One possible solution might be to modify drug withdrawal periods. Such an approach would require scientific data to be developed on how the resistance profiles of microbial populations in animals changes in response to the elimination of a drug. Work involving resistance to traditional preservation technologies and antibiotic drug resistance must be based on a sound understanding of microbial, physiologic, and genetic adaptive mechanisms.

FY98 Activities with Food-Safety Initiative Funds

- FDA and ARS will conduct research to identify and characterize the factors that lead to the development of multiple drug (antibiotic) resistance in foodborne pathogens in farm and aquaculture animals, including establishing the gene-transfer mechanisms and selective pressures.

- ARS and FDA will investigate techniques for manipulating the microbial ecology of the intestinal tract of agricultural and aquaculture animals to prevent the development of antibiotic resistance or select for nonresistance. Research will emphasize competitive exclusion techniques (probiotics) and the use of extended drug-withdrawal periods. Probiotics are benign bacteria that can be used to out-compete pathogenic bacteria.

Prevention Techniques: Pathogen Avoidance, Reduction, and Elimination

Contaminants are introduced into the food supply at numerous points along the way from farm to table. Food animals and their manures can carry human pathogens, without any clinical manifestations. Likewise, fresh fruits, fresh vegetables, and grains can harbor pathogens or mycotoxins without any discernable loss of quality. In such cases, traditional approaches of segregating contaminated foods are ineffective, and active interventions are needed. In particular, new interventions are needed to prevent and control the pathogens listed below in raw agricultural commodities and seafood. Developments in this area would be expected to provide new approaches for controlling a variety of other foodborne contaminants.

FY98 Activities with Food-Safety Initiative Funds

For *Campylobacter*, *Salmonella*, *Toxoplasma*, *E. coli* O157:H7, and other Shiga-like toxin-producing *E. coli*, and *Cryptosporidium*, FDA and ARS, often in partnership with universities and industry, will:

- Expand research into the microbial ecology of foodborne pathogens and how initial colonization in plants and animals can be prevented.
- Expand research on new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from agricultural and aquaculture animals before slaughter or harvest, including the use of probiotics.
- Develop new methods to reduce or eliminate pathogenic microorganisms and mycotoxins from plants before harvest.
- Develop new disinfection methods and systems for improved sanitation of production (including on-farm) processing and marketing equipment and facilities.
- Expand research on new methods of decontamination of meat, poultry, seafood, fresh produce, and eggs.
- Initiate research to develop new techniques for eliminating animal feeds as a source of foodborne pathogens.

Long-term Activities

- ARS, CSREES, and FDA should undertake research to develop new decontamination methods for contaminants such as *Vibrio* and Norwalk virus on or in marine-harvested and aquaculture-reared seafood, and for *Cyclospora* and hepatitis A virus on fresh produce.
- ARS, CREES, and FDA should work with industry and academia to develop new techniques that provide alternatives to traditional thermal processing for eliminating pathogens. Collaboration among these parties, particularly with industry participation, will facilitate rapid evaluation of the safety and effectiveness of new technologies, and ultimately, approval of processes.
- FDA, FSIS, and EPA should work with industry and academia to develop criteria for evaluating the efficacy and safety of the new intervention technologies.

Food Handling, Distribution, and Storage

Food production, processing, and consumption often occur thousands of miles apart. Stresses associated with the transportation of live animals and fresh produce can contribute to the dissemination of foodborne pathogens. Effective packaging and proper food-storage conditions are critical to maintaining the level of safety achieved by processing.

Long-term Activities

- ARS, CSREES, and FDA should undertake research to identify factors that contribute to the spread of microorganisms during transportation of live animals and fresh produce and develop techniques for eliminating cross-contamination.

- FDA, ARS, and CSREES should work with industry and academia to develop and assess the effectiveness of in- or on-package sensors of storage conditions to alert consumers of products not stored safely.

Charge an Interagency Committee Convened by the Office of Science and Technology Policy (OSTP) to Coordinate Federal Research Priorities and Planning

Numerous opportunities exist for collaboration and the development of research partnerships among federal and state agencies, the private sector, and academia. A mechanism is needed to coordinate food-safety research among federal agencies, to link research with the activities and needs of the agencies, to better leverage agency resources and experience, and avoid duplication of effort. Such a coordination mechanism could be provided by an OSTP-convened interagency committee. That committee would review food-safety responsibilities and research programs of the various agencies with a view to recommending direction of research funds and programs in accordance with those responsibilities.

IMPROVING INSPECTIONS AND COMPLIANCE

Background

Inspection of commercial food processors is an integral part of the food-safety assurance system. Inspections are carried out by federal, state and local authorities. In addition to other food-inspection responsibilities, state and local officials also have primary responsibility for inspecting restaurants, supermarkets, and other retail establishments. At the federal level, FSIS has responsibility for meat and poultry inspection in slaughter and processing plants and egg-product-processing plants, and for all imported meat, poultry, and egg products. FDA conducts periodic, random inspections of all other food-processing plants; that entails fewer than 700 inspectors and laboratory personnel for 53,000 U.S. plants and for all other imported foods.

Problem

The number of inspections conducted by FDA has decreased steadily since 1981, when 21,000 inspections were conducted, so that today resources exist to carry out only about 5,000 inspections per year. An FDA-regulated plant is inspected by FDA, on average, only once every 10 years. FDA also relies upon the states to conduct some inspections under contract, but that number has dropped from 12,000 in 1985 to 5,000 now. Moreover, because the number of imports has doubled over 5 years, with no real increase in inspectors, a smaller percentage of imports are inspected at entry.

Given the limited inspection coverage, FDA is finding an increasing number of problems--the number of products recalled for life-threatening microbial contamination has increased almost five-fold since 1988. Federal budget constraints will likely prohibit significant funding increases in the future, so FDA must find new ways to provide adequate inspection coverage.

Recommendations

Scientists and other food-safety experts have concluded that the most effective and efficient mechanism to ensure that food processors identify and control hazards that could threaten food is the application of HACCP principles. FDA's seafood HACCP regulations go into effect in December 1997. FSIS began to implement its HACCP and Pathogen Reduction Requirements for the meat and poultry industries in 1997 with phase-in to be completed in 2000. HACCP programs allow government and industry resources to be used more appropriately, allowing the government and industry to focus on the greatest risks. To ensure that HACCP is properly implemented, and to ensure more efficient and effective monitoring of the safety of the food supply, recommendations are being made in the following areas.

ahance Development of HACCP Procedures

FY97 Activities:

- Based on the best science available, FDA will propose appropriate regulatory and non-regulatory options, including HACCP, for the manufacture of fruit and vegetable juice products.

- Based on the best science available, FSIS will propose appropriate regulatory and non-regulatory options, including HACCP, for egg products.

- FDA and USDA will immediately identify preventive measures to address public-health problems, such as those recently associated with fruits and vegetables, e.g., hepatitis A virus associated with frozen strawberries. This will be accomplished through a comprehensive review of current production and food-safety programs including inspection, sampling, and analytical methods.

- FSIS and FDA will jointly publish an ANPR in which they will evaluate the public-health, food-technology, and regulatory issues involved in reducing the risk of human illness from *Salmonella* Enteritidis in shell eggs. The ANPR will solicit information and comment on all elements of risk in the farm-to-table chain to ensure any resulting regulatory actions will be both reasonable and effective in reducing risk.

- FDA will evaluate whether and how to propose to require the use of HACCP in other appropriate food commodities and animal feeds.

- FDA will provide additional training in seafood HACCP and FSIS will complete HACCP training of inspectors in large meat and poultry plants.

- FSIS and FDA will evaluate expanding existing cooperative agreements so that plants producing meat and nonmeat foods are inspected by FSIS inspectors trained in FDA inspection standards. FSIS inspectors are already in these plants, and their presence could be better used to maximize use of federal resources without loss of inspection coverage for FSIS-regulated foods.

- FSIS will conduct a series of public meetings to discuss:

    - How HACCP requirements will be implemented in slaughter plants and how the roles and responsibilities of inspection personnel will change with that implementation.

- The design and testing of new inspection concepts consistent with HACCP principles to achieve food-safety and other consumer-protection objectives through distribution and retail channels to consumers.

- FSIS and state associations will complete development of HACCP-based control measures for meat and poultry processing at the retail level.

FY98 Activities with Food-Safety Initiative Funds

- FDA and USDA will cooperate in evaluating the feasibility of HACCP for commodities such as fresh fruit and vegetables. The process could also consider whether it is appropriate to use USDA inspectors to inspect plants that manufacture products regulated by both agencies or even products that must meet different regulatory requirements from the two agencies, such as fresh produce used in the school lunch program.

- FDA will implement seafood HACCP by hiring approximately 80 investigators to conduct inspections to ensure proper implementation of seafood HACCP.

- A performance-based organization (PBO), will be created, with Congressional approval, as the organizational structure for the voluntary fee-for-service seafood program currently located at the Department of Commerce's National Marine Fisheries Service. The Departments of Commerce and Health and Human Services will consider whether to locate the PBO at FDA, which would consolidate voluntary and mandatory seafood programs within one agency and provide limited additional resources for implementation of seafood HACCP, while continuing the voluntary fee-for-service program.

- FSIS will continue to propose changes to current regulations to harmonize with HACCP.

Long-term Activities

- FDA should further the use of HACCP principles, as appropriate, for other foods, including animal feeds, and use risk-assessment techniques where possible.

Enhance the Safety of Foods in Retail Food Establishments Particularly at State and Local Levels

More than 3,000 state and local regulatory agencies have primary responsibility for monitoring retail food establishments to ensure that consumers are protected. U.S. retail establishments include approximately 785,000 commercial and institutional food establishments, 128,000 grocery and convenience stores, and 1.5 million vending operations. Workers in these establishments have highly diverse backgrounds and training.

FY97 Activities

- FDA and FSIS will hold a series of meetings with state and local regulators in five regions to establish retail program standards in accordance with the 1997 model state code (the Food Code) to enhance national uniformity.

FY98 Activities with Food-Safety Initiative Funds

- FSIS and FDA will provide HACCP training to state and local inspectors that will augment the training program for federal inspection personnel, more fully covering the farm-to-table process.

- See also "Education: Improve Retail Food-Service and Institutional Education."

Long-term Activities

- The Food Code should be adopted by all 50 states.

Enhance Federal-State Inspection Partnerships

State inspection programs are an important component of the nation's food-safety inspection system. The move toward HACCP will pose a challenge to the states that federal agencies can help the state system to meet. If HACCP is to be an effective program for ensuring that food processors have modern, state-of-the-art food-safety procedures in effect, FDA must improve its inspection capabilities, so that the highest-risk food plants are inspected at least once per year. New federal-state partnerships focused on coordinating inspection coverage (particularly between FDA and the states), are major steps in this direction.

FY97 Activities

- FSIS will hold two public meetings on the issue of interstate distribution of state-inspected meat and poultry products. The purpose of these public meetings is to obtain information and comment from all stakeholders on this issue.

FY98 Activities with Food-Safety Initiative Funds

- FDA will develop additional federal-state partnerships to improve coordination between the federal food-safety agencies and state regulators for the training of state inspectors in food-safety standards applicable at all levels, including retail. FDA is currently involved in 92 partnerships with states; approximately 30 of those deal with inspection activities.

- FDA will expand the number of federal-state partnerships to include more extensive HACCP training of state inspectors, the seafood industry, and the retail food industry.

- FSIS will initiate HACCP training for state inspectors with respect to meat and poultry products.

Long-term Activities

- FDA and FSIS should work more closely with industry, professional and trade associations, and academia to ensure effective implementation of HACCP principles, particularly at the production, processing, and retail levels.

- FDA should create a data system to compile inspection data from federal and state inspections, as well as provide the states with equipment and technology for the rapid sharing of inspection results.

Enhance Coverage of Imported Foods with Specific Attention to Foods Regulated by FDA

Wharf examinations and sampling of foods being offered for import into the United States have dropped by 50% in just the past four years. Today, FDA is responsible for about 2.2 million import food entries (i.e., shipments), an increase from 1.5 million entries just 5 years ago, with the same number of staff.

FY98 Activities with Food-Safety Initiative Funds

- FDA will work to increase the number of mutual recognition agreements (MRAs) with trading partners. Under MRAs, the trading countries ensure that food is produced and manufactured under equivalent systems that provide a comparable level of safety.

- FDA will initiate a federal-state communication system through which states can inform federal agencies of problems found with imported products in their jurisdictions.

- FDA will initiate a system for certifying and accrediting private laboratories, including use of a quality-assurance procedure, that will be authorized to test samples of food products for contaminants. Such private parties would provide a service to food firms wishing to demonstrate that their products meet applicable federal standards.

- When FDA and FSIS become aware of possible public-health problems associated with a regulated food product (e.g., through occurrence of foodborne illness outbreaks, sample analysis, or inspections), the agencies will provide technical assistance to the foreign country importing the product.

Long-term Activities

- FSIS should continue to verify foreign government-inspection progress for conformance with the new HACCP and Pathogen Reduction Requirements; that activity will begin in 1997 and should be completed in 2000.

- The laboratory-certification process should be extended to include assessing the utility of existing accrediting bodies with FDA providing performance standards and oversight to the process.

- FDA should expand the federal-state communication system states use to inform federal agencies of problems found with imported products in their jurisdictions. As part of that expansion, FDA should evaluate the feasibility of combining the communication system with the federal-state inspection data system discussed above, making the data and information more widely accessible.

- FDA should review and evaluate ways to increase coverage of imports through such means as increased personnel, increased partnerships, or innovative information-sharing with the states.

nhance Safety of Foods During Transportation

considering whether and how to regulate the transportation of meat, poultry, seafood, eggs, nd other foods to safeguard the public from pathogenic microorganisms and other hazards, FSIS nd FDA published an ANPR on November 22, 1996.

FY98 Activities with Food-Safety Initiative Funds

- FDA and FSIS will evaluate the comments and information received in response to the ANPR as a basis for determining what, if any, regulatory approach to take, including development of guidelines. These guidelines may include such elements as suggested performance standards for temperature control, providing information on prior cargo, and cleaning information for the food-shipper's use, to ensure the safety of the food at its destination.

Long-term Activities

- FDA and FSIS, through partnerships with states, should provide training and training materials to the transportation industry on safe food transportation. (See "Education: Improve Industry Education in the Transportation Area.")

EDUCATION

Background

An integral part of the overall food-safety initiative is providing food-safety education to a variety of audiences: consumers (the general public and specific groups at risk for foodborne illness); public-health professionals and physicians; retail, food-service, and institutional food preparers; veterinarians, animal and other food producers; and food-transportation workers. The challenge is to create educational messages that address the risks relevant to each audience throughout the food chain. Research and risk assessment are important elements in identifying these risks and devising appropriate messages. Realizing that educational efforts are cost-effective investments, federal, state and local governments, private organizations, consumer groups, and industry have fostered educational programs to address foodborne illness.

Problem

Despite educational efforts, foodborne illness remains prevalent throughout the United States. For example, from 1988 to 1992, *Salmonella* caused 69% of the 796 bacterial foodborne disease outbreaks; 60% of those *Salmonella* outbreaks were caused by *Salmonella* Enteritidis. *S.* Enteritidis also resulted in more deaths than any other pathogen, with 85% of these deaths occurring among residents of nursing homes.

One reason is that food preparers and handlers at each stage of the food chain lack the knowledge of risks involved and the related safe food-handling practices. Food preparers in the retail sector must be made aware of how they can prevent food contamination and reduce pathogen growth, particularly by preventing cross-contamination with other foods and by properly cooking foods such as eggs. Without the knowledge of food-safety practices and proper food-handling procedures, foodborne illness cannot be significantly reduced. Food-safety messages should be developed to reach individuals at each stage from the farm to the table.

Risk assessment and research are needed to determine the most effective ways to overcome barriers to use of safe food-handling practices and to ensure use of safe food-handling practices by specific audiences. Consumers' food-handling practices and the choices they make in the foods they eat will either increase or decrease the chances of foodborne illness. Studies show that more than 50% of the public eats raw or undercooked eggs, 23% eats undercooked hamburger, 17% eats raw clams and oysters, and 26% do not wash cutting boards after using them for raw meat or poultry.

Health professionals and physicians also need specific knowledge about causes and effects of foodborne illness to more effectively detect and treat the illnesses. Producers of animals used in human food production and veterinarians treating such animals must be made aware of food-safety aspects of drugs and drug residues. Finally, those responsible for the transportation of food are often unaware that mishandling of food during shipment can result in contamination.

Recommendations

The goal of this initiative is to target and change unsafe food-handling practices by people throughout the food chain, including food-service workers, and especially those providing food to populations at high risk of foodborne illness. Objectives include: 1) forming partnerships and alliances to maximize resources and broaden the impact and scope of educational efforts; 2) designing messages by conducting research to identify barriers to safe food handling, upon which educational programs will be centered; and 3) expanding the use of innovative outreach methods, including the use of new technologies.

Implementation of the education goals and objectives of the initiative combined with the other elements of the initiative will significantly increase the number of consumers and food-service workers being reached with effective and persuasive food-safety messages.

Improve Consumer, Retail, and Food Service Education

FY97 Activities

The 1997 Consumer Food-Safety Education Partnership

A memorandum of understanding was signed in May 1997, formalizing a food-safety education partnership that includes industry, consumer groups, FDA, CDC, USDA, and the Department of Education. Participants in the partnership will launch a nationwide food-safety education campaign for the general public. The campaign will center on four key food-safety concepts tested for maximum consumer understanding and will include a slogan, logo or identifiable character. At present, the Partnership is reviewing proposals from national public-relations and communications firms to conduct a public awareness and education campaign. The industry groups have contributed almost $500,000 to date. Plans for the nationwide campaign will be announced at the food-safety education conference, *"Changing Strategies: Changing Behaviors,"* sponsored by FSIS, CSREES, FDA, and CDC to be held June 12-13 in Washington, DC. The partnership will promote September as National Food Safety Month, as already designated by industry, and launch the food-safety education campaign during the month.

Identify key food-safety education principles through establishment of an expert council

Convene the National Food Safety Education Council, an independent scientific review board to periodically review food-safety education messages. The Council, which will include food scientists and educators, will serve to identify emerging food-safety risks that require public education. Risk assessment will be used to identify at-risk audiences for targeted food-safety education programs.

Other FY97 Activities

- The agencies will form alliances with industry, consumer, trade, state and local food-protection agencies, and academic organizations to share food-safety education materials and conduct joint food-safety education activities in order to leverage resources and expand the reach of the alliances. For example, FDA, FSIS, and CSREES will form an alliance, joining expertise of federal, state and local agencies, industry, and professional and trade associations to promote and implement the 1997 Food Code and develop multilingual communication techniques targeted to specific groups to overcome communication barriers.

- See "Inspections: Enhance Safety of Foods in Retail Food Establishments."

FY98 Activities with Food-Safety Initiative Funds

- FDA, CDC, FSIS, and CSREES will promote and incorporate food-safety education into school programs.

Conduct Research to Identify Barriers to Safe Food-Handling, Upon Which Educational Programs Will Be Centered

FY97 Activities

Under the auspices of the National Food Safety Education Council:

- HHS and USDA will develop national safe-food-handling guidelines like the Dietary Guidelines and review them periodically.

FY98 Activities with Food-Safety Initiative Funds

- Conduct additional research necessary to determine the best way to communicate key food-safety principles in order to achieve behavior change.

- Conduct research necessary to develop a visual communication tool that conveys food-safety principles, as the food guide pyramid does for nutrition principles.

Long-term Activities

- Through partnerships and alliances, implement an education campaign to use the new educational tools especially targeted to school programs and specific at-risk audiences.

Expand Existing Information Systems

FY97 Activities

- Expand existing information systems, such as the existing Foodborne Illness Education Information Center, while laying the groundwork for a National Clearinghouse for Food Safety Education. Innovative methods for sharing food-safety information will be explored, including the consolidation of government food-safety Internet sites to reach larger audiences and provide easier access to information through a single site.

FY98 Activities with Food-Safety Initiative Funds

- Establish the National Clearinghouse for Food Safety Education.
- Consider use of food labels and other point-of-sale materials to convey food-safety information.
- In food service, develop and initiate a highly focused multilingual program to change food workers' unsafe food-preparation behaviors. The programs will address the impact of the high turnover in food-service workers and target teenage workers, small businesses, and new entrepreneurs.

Long-term Activities

- Evaluate program and continue to support those programs initiated in FY97 and FY98.

Improve Veterinarian and Producer Education

Long-term Activities

- Use existing mechanisms, such as the Cooperative Extension Service and professional associations, to strengthen and implement programs to educate producers, veterinarians, and state and local regulators about proper drug use and the incorporation of HACCP principles into industry quality-assurance programs to reduce foodborne pathogens.
- Encourage the evaluation and improvement of veterinary and producer education at veterinary and agriculture colleges to address foodborne pathogens in animals and their manures.
- Develop and disseminate guidelines and educational materials through existing networks to food producers and the veterinary medical community.

Improve Health-Professional Education

Long-term Activities

- In cooperation with FDA , FSIS, and CSREES, CDC should train public-health professionals on foodborne disease and clinical microbiology and foodborne illnesses with nontraditional symptoms by using multimedia and distance-learning techniques and the National Laboratory Training Network.

Improve Industry Education in the Transportation Area

Long-term Activities

- Form an alliance among government agencies and the private sector to develop educational materials and train food-transportation vehicle owners and operators and food-processing establishments on hazards associated with the transportation of food products, particularly hazards associated with temperature control, prior cargo, and sanitation methods.

- See also: "Inspections: Enhance Safety of Foods During Transportation."

A BLUEPRINT FOR A BETTER FOOD-SAFETY SYSTEM

Background

The actions described in this report will significantly improve the safety of the nation's food supply, but the agencies recognize that this 90-day report does not address a number of critical issues facing our food-safety programs. The agencies recommend a longer-term strategic planning effort to consider how to best address important challenges and make the best use of the agencies' limited resources. This process will involve all public and private stakeholders, including consumer groups, affected families, state and local governments, and industry. One function of the strategic-planning process is to consider how to make the best use of each agency's limited resources.

Through this initiative, and previous activities, we have laid the groundwork for a strategic planning effort. For example, federal agencies, consumer groups, and industry have worked together to incorporate HACCP into meat, poultry, and seafood regulatory programs. And there is now a broad recognition of the need to carefully implement these programs, and to consider how to apply preventive measures in other areas of concern. A strategic-planning effort could build on this common ground, and tackle some of the difficult public-health, resource, and management questions facing federal food-safety agencies.

As discussed throughout this report, USDA, HHS, and EPA have responsibilities for ensuring the safety of the U.S. food supply. USDA and HHS also have ancillary responsibilities for the quality of our food. These responsibilities include the grading of agricultural commodities and grain by the Agricultural Marketing Service and the Grain Inspection Service, the importation of foreign plants and animals by APHIS, and the quality and wholesomeness of food purchased by the federal school lunch program. FDA sets standards of quality for a variety of food products. Regulatory requirements applicable to food products are largely established by FSIS for meat, poultry and egg products, and by FDA for all other products.

In recent years, there has been increasing evidence that foodborne diseases can be caused by microbial contamination in seafood, fresh fruits, vegetables, and other products. Moreover, during the Clinton Administration, both agencies have looked to a new and similar approach to food regulation. FSIS has adopted HACCP for the products that it regulates and FDA has adopted HACCP for seafood products, and is considering the HACCP approach for other products. During the next few years, the HACCP regulations that these agencies have adopted will go into effect, and more may well follow.

Developing a Strategic Plan

Over the past 90 days, the federal food-safety agencies have engaged a wide range of stakeholders in discussions about food-safety issues through a series of public meetings and through written comments to public dockets. Although these discussions have identified some ideas for

approaches to strategic planning, they have more clearly established the need for continuing discussions about the process for developing a strategic plan.

Therefore, the agencies will initiate a longer-term strategic planning process to develop a strategic plan for improving the food-safety system. The process will facilitate the participation of all interested parties. Extensive, structured discussions will be needed to build trust in the process, and to obtain agreement on priorities, strategies for achieving change, and ways for measuring progress.

Because it is critical that the process be inclusive and equitable, the agencies will give interested parties an opportunity to comment on the possible approaches for structuring the dialogue before its implementation. The agencies will provide specific information regarding the general objective, scope, and conduct of the dialogue and strategic-planning process, management of the process, selection criteria for participants, and other relevant factors. Unanimous agreement is unlikely. Therefore, the agencies will use a general consensus to shape the planning process.

Broad participation of stakeholders is central to the success of the discussions. The achievement of such broad participation can be accomplished in a number of ways. The agencies will hold meetings in various regions of the United States, which will also ensure broad participation. These meetings will involve multiple sectors to ensure broad and balanced participation of all stakeholders in the food-safety system. The meetings will be open and their proceedings, products, and the process for producing those products transparent.

Issues for Consideration

A major challenge in developing a strategic plan will be attaining consensus on priorities for action to enhance food safety within the highly complex food-safety oversight system. Reaching agreement on priorities is compounded by the complexity of the food supply and the different perspectives of the various oversight agencies and groups. Federal and state agencies have established programs in research, risk assessment, education, surveillance, and inspection, and agencies are working to better coordinate activities within these programs. Nevertheless, a better system of identifying and setting priorities within these areas is essential to maximizing the use and effect of limited agency resources in reducing the incidence of foodborne illness and enhancing the safety of the food supply.

During the course of the stakeholder discussions, a variety of issues, ranging from specific to broad, surfaced as priority topics for discussion. A number of stakeholders suggested the need to consider such broad policy questions as:

- Key public-health, resource, and management questions facing federal food-safety agencies.
- Structure of strategic, coordinated, long-range risk-assessment and research agendas.

- Consideration of improvements for coordination and planning of food-safety regulation to optimize federal and state prevention, intervention, and control actions.

- Means to improve exchange of information about foodborne disease outbreaks.

More focused, technical issues were also suggested for consideration, among them:

- Technical and policy issues associated with agricultural manures (important potential sources of microbial contaminants of foods). Animal manures are currently excluded from regulation. Therefore, an EPA regulatory mechanism to control human health impacts resulting from improper application to or burial of manures in farm and other lands does not exist.

- Technical and policy issues associated with microbial-control technologies, including food irradiation.

- Developing a global approach to evaluating new, emerging, and potential foodborne diseases such as Transmissible (Bovine) Spongiform Encephalopathy--T(B)SE--and a process for responding to prevent the spread of such diseases.

Prepare a 3- to 5-Year Strategic Plan

Participants in the planning process would be charged with developing a strategic long-range agenda that could be used to help set priorities, improve coordination and efficiency, identify gaps in the current system, and enhance and strengthen prevention and intervention strategies, and identify measures to show progress. Each agency will incorporate the relevant parts of the strategic plan into its Government Performance and Results Act (GPRA) strategic plan, commensurate with its budget.

Measure Progress to Evaluate the Effectiveness of the Plan in Reducing the Annual Incidence of Foodborne Illness

After the plan's implementation, progress would be reviewed to determine the strategic plan's effect on reducing the annual incidence of foodborne illness. Measurable goals and objectives would provide a basis for establishing progress. Measurements could be based on a decline in the number of foodborne illnesses and deaths, a decline in the number of outbreaks, more effective prevention and intervention programs, more rapid, coordinated, and effective responses to foodborne illness outbreaks, increases in inspection coverage for domestic and imported products, changes in behavior, and better detection and quantification methodologies.

APPENDIX A

FY98 Budget -- Food Safety Initiative

HHS:

Food and Drug Administration		
Foods:		
Surveillance		1,660,000
	Monitoring pathogen levels	
	Support sentinel sites	
Coordination		550,000
Risk Assessment		3,950,000
	Risk assessment consortium	
	Exposure assessment	
Research		3,900,000
	Analytical Methods	
	Pathogen Control	
	Food Handling	
Inspections		7,870,000
	Implement seafood HACCP	
	State partnerships	
	Lab certification	
Education		2,070,000
	Consumer/retail education	
	Total Foods	**20,000,000**
Animal Drugs and Feeds:		
Surveillance		1,500,000
Research		2,500,000
	Total Animal Drugs & Feeds	**4,000,000**
Centers for Disease Control:		
Surveillance		10,000,000
	Total, HHS	**34,000,000**

USDA:

Agricultural Research Service		
Research		4,114,000
Cooperative State Research, Education and Extension Service		
Research		2,000,000
Education		2,000,000
	Total, CSREES	**4,000,000**
Food Safety and Inspection Service		
Surveillance		500,000
Inspections		565,000
	Total, FSIS	**1,065,000**
	Total, USDA	**9,179,000**
	Total Initiative	**43,179,000**

APPENDIX B

SOME IMPORTANT MICROBIAL PATHOGENS ASSOCIATED WITH FOODBORNE ILLNESS

Bacteria

Salmonella

Salmonella species cause diarrhea and systemic infections, which can be fatal in particularly susceptible persons, such as the immunocompromised, the very young, and the elderly. Animals used for food production are common carriers of salmonellae, which can subsequently contaminate foods, such as meat, dairy products, and eggs. Foods often implicated in outbreaks include poultry and poultry products, meat and meat products, dairy products, egg products, seafood, and fresh produce. An estimated 800,000 to 4 million infections occur each year in the United States, most of them as individual cases apparently unrelated to outbreaks. Between 128,000 and 640,000 of those infections are associated with *Salmonella* Enteritidis in eggs. Over the past decade, more than 500 outbreaks have been attributed to *S.* Enteritidis with more than 70 deaths. In 1994, an estimated 224,000 people became ill from consuming ice cream in one outbreak alone.

Campylobacter

The bacterium *Campylobacter* is the most frequently identified cause of acute infectious diarrhea in developed countries and is the most commonly isolated bacterial intestinal pathogen in the United States. It has been estimated that between 2 and 4 million cases of campylobacteriosis occur each year with an associated 120-360 deaths. *Campylobacter jejuni* and *Campylobacter coli* (two closely related species) are commonly foodborne, and are the infectious agents most frequently described in association with Guillain-Barré syndrome, as frequently as 1 in 1000 cases. Several prospective studies have implicated raw or undercooked chicken as major sources of *C. jejuni/coli* infections. Unpasteurized milk and untreated water have also caused outbreaks of disease.

Shiga-like toxin-producing *Escherichia coli*

Several strains of the bacterium *E. coli* cause a variety of diseases in humans and animals. *E. coli* O157:H7 is a type associated with a particularly severe form of human disease. *E. coli* O157:H7 causes hemorrhagic colitis, which begins with watery diarrhea and severe abdominal pain and rapidly progresses to passage of bloody stools. It has been associated with HUS, a life-threatening complication of hemorrhagic colitis characterized by acute kidney failure that is particularly serious in young children. *E. coli* O157:H7 is found in cattle, but there may be other reservoirs; the dynamics of *E. coli* O157:H7 in food-producing animals are not well understood. Approximately 25,000 cases of foodborne illness can be attributed to *E. coli* O157:H7 each year with as many as 100 deaths resulting. *E. coli* O157:H7 outbreaks have recently been associated with ground beef, raw milk, lettuce, and minimally processed and fresh fruit juices. The most recent outbreak in the Fall of 1996 in three western states and British Columbia was associated with unpasteurized apple juice, sickened 66 people, and caused the death of one child.

Vibrio

Vibrio species are gram-negative bacteria most commonly associated with seafood-containing dishes. *Vibrio parahemolyticus* is the species that is most commonly reported as a cause of foodborne disease; it generally causes watery diarrhea and abdominal pain lasting 1-7 days, and commonly follows consumption of improperly handled cold-seafood salads. *V. vulnificus* is one of the more serious foodborne pathogens, with a case-fatality rate for invasive disease that exceeds 50%. Most cases of foodborne *V. vulnificus* infections occur in persons with underlying illness, particularly liver disorders, who eat raw molluscan shellfish. Since the late 1980s, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Gulf Coast states have intensified efforts to collect information on *Vibrio* infections, and on the microorganisms' ecology, to improve our ability to prevent foodborne infections.

Protozoa

Toxoplasma gondii

T. gondii is a parasitic protozoan. Some 1.4 million cases of toxoplasmosis occur annually with an associated 310 deaths. Healthy adults who become infected usually have no symptoms but might get diarrhea. Pregnant women who become infected can pass the disease to their fetuses. In infants infected before birth, fatality is common. Should the infant survive, the effects of infection are typically severe (i.e., mental retardation). The disease can be life-threatening in persons with weakened immune systems and often is fatal to people with HIV/AIDS. *T. gondii* has been found in virtually all food animals. The two primary ways that humans become infected are consumption of raw or undercooked meat containing *T. gondii* or contact with cats that shed cysts in their feces during acute infection. Under some conditions, the consumption of unwashed fruits and vegetables can contribute to infections.

Cryptosporidium parvum

C. parvum is a parasitic protozoan. The most common consequence of infection in healthy people is profuse watery diarrhea lasting up to several weeks. Children are particularly susceptible. Cryptosporidiosis can be life-threatening among people with weakened immune systems. The largest recorded outbreak of Cryptosporidiosis was a waterborne outbreak in Milwaukee, Wisconsin, in 1993, affecting more than 400,000 people. More recently, a waterborne outbreak in Las Vegas resulted in at least 20 deaths. The first large outbreak of cryptosporidiosis from a contaminated food occurred in 1993. That outbreak was attributed to fresh-pressed apple cider. *Cryptosporidium* also is found in animal manures.

Viruses

Norwalk virus

Norwalk viruses are important causes of sporadic and epidemic gastrointestinal disease that involve overwhelming, dehydrating diarrhea. An estimated 181,000 cases occur annually with no known associated deaths. In January 1995, a multistate outbreak of

viral gastroenteritis due to Norwalk virus was associated with the consumption of oysters. A 1993 Louisiana outbreak of Norwalk virus gastroenteritis involved 70 ill people and was associated with the consumption of raw oysters. In 1992, another outbreak resulted in 250 cases. Outbreaks of Norwalk virus intestinal disease have been linked to contaminated water and ice, salads, frosting, shellfish, and person-to-person contact, although the most common food source is shellfish. Several such outbreaks are believed to have been caused by oysters contaminated by sewage dumped overboard by oyster harvesters and recreational boaters.

Hepatitis A

Hepatitis A (HAV) is a virus that infects the liver and causes hepatitis A, an illness with an abrupt onset that can include fever, malaise, nausea, abdominal discomfort, dark urine, and jaundice after a prolonged incubation period (e.g, more than 2 months). In children less than 6 years old, most (70%) infections are asymptomatic, but in older children and adults, infection is usually symptomatic, with jaundice occurring in more than 70% of patients. Signs and symptoms of hepatitis A usually last more than 2 months, and there are no chronic consequences. About 130,000 infections with HAV and 100 deaths occur each year in the United States. The primary mode of transmission for HAV is person-to-person by the fecal-oral route. Recognized foodborne hepatitis A outbreaks account for only 2% to 5% of hepatitis A cases reported in the United States each year, most of which are caused by an infected food handler. Outbreaks due to foods contaminated before preparation, while uncommon, have been associated with widely distributed products such as shellfish, lettuce, frozen raspberries, and frozen strawberries. Hepatitis A can be prevented by good personal hygiene and safe food-handling practices. It can also be prevented before exposure by hepatitis A vaccine, and after exposure by immune globulin, if given within 14 days of exposure.

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 6

WRITTEN STATEMENT

OF THE

GUATEMALAN HIGH LEVEL COMMISSION
FOR FOOD SAFETY:

"BERRY PRODUCTION IN GUATEMALA AND THE
MODEL PLAN OF EXCELLENCE - MPE"

PRESENTED TO THE

SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS

UNITED STATES SENATE
WASHINGTON, D.C. SEPTEMBER 24 and 25, 1998

Summary

The High Level Commission for Food Safety (HLC) was created in late 1997 to develop an oversight framework to ensure that Guatemala's agricultural exports meet the highest sanitary and quality standards. In the case of raspberries, the Ministries of Agriculture, Health and Economy, together with the president of the Non-Traditional Products Exporters Association (AGEXPRONT) and the president of the Guatemalan Berry Commission (GBC) preside over the Commission.

In ensuring that raspberries meet the highest sanitary and quality standards, they created a comprehensive and strict program called the Model Plan of Excellence (MPE). Its operative oversight is the responsibility of the Agricultural & Environmental Integral Protection Program (PIPAA) – a public and private sector joint commission – that performs the farms' and plants' inspection, certification and verification.

The MPE requires that by March 15, 1999 all raspberry exporters wishing to export *must* fully implement and comply with the MPE's stringent standards.

History

In 1990, the Center for Disease Control (CDC) first reported cyclospora outbreaks associated to water in the U.S. However, it was not until 1996 and 1997 that fresh produce consumption – including Guatemalan raspberries – was epidemiologically linked to cyclospora cayetanensis in some of the outbreaks. CDC and Food and Drug Administration (FDA) scientific data show that there is imprecision regarding the source, biology and virulence of this little known emerging pathogen. It has not been detected in raspberries or in any common practice involving any of the procedures in raspberry growing, handling, or exporting.

FDA's and CDC's reports state that it seems to be a seasonal illness, occurring during spring and early summer seasons; based on their findings, Guatemala decided to voluntarily suspend the exports of raspberries to the U.S. during those months. It is noteworthy to mention that in the past three years Guatemala has exported approximately 500,000 raspberry flats during the late summer, fall, and winter seasons without incident.

Guatemala has fully cooperated with CDC and FDA officials in their investigations to find a solution to this worldwide problem. Since 1997 Guatemalan raspberry growers have taken a proactive stance to find the source of contamination and started to upgrade their sanitary and quality assurance systems in raspberry farms based on the recommendations and cooperation of FDA, CDC and the Food Marketing Institute (FMI).

Background on the MPE

Under the direction of the HLC and other parties involved, the MPE was conceived in November of 1997 and finalized in March of 1998. Since, FDA and FMI have revised it on several occasions, and finally it is scheduled for its full implementation in the upcoming months. The MPE evolved from the improvement of early sanitary measures and from the inclusion of new ideas. The result is a unique program in the world whose sanitary standards surpass those of current or proposed programs.

The operative oversight of the MPE is the responsibility of the Agricultural & Environmental Integral Protection Program (PIPAA). PIPAA is a public and private sector joint commission that is responsible for carrying out farms' and plants' inspection, certification and verification.

PIPAA is one of the working groups created within the High Level Commission for Food Safety to address food safety concerns. Some of the other groups directly address the areas of research, epidemiology and environment, and post-harvest treatment evaluation. Within these working groups, the Commission has incorporated expert oversight groups that include FDA, CDC, and international scientists and universities.

As a result of its evolution, the MPE includes technical aspects of the first program – the Sanitary and Quality Assurance Program. Hence, it incorporates Hazard Analysis of Critical Control Points (HACCP), Good Agricultural and Good Manufacturing Practices (GAP/GMP), water quality, infrastructure, and transportation standards which make the MPE even stricter than the FDA's future GAP/GMP Voluntary Guide for Fresh Fruit and Vegetables.

It also provides clear guidelines and keeps farms and plants records on water supply, hygiene, irrigation, fertilizer and pesticide utilization, harvesting, packaging, and storage and distribution of product, among others. Many of these farms and plants records are then captured in codes that allow for the trace-back of the product's origin.

The MPE calls for additional employee training on health and hygiene principles, monitoring of employees' health for the eradication of potential risk factors, and further control of the fruit's origin. The latter implies stricter PIPAA farm, shipment points, and transportation inspections. The MPE also regulates the proper issuance of export licenses to the selected exporting plants, and also conducts origin-verification inspections at a one of a kind import/export airport warehouse facility for the handling of air shipments. In order to strengthen the trace-back capability, a trace-through function is added to track the product to its destination.

Furthermore, based on FDA's and CDC's current scientific information that cyclospora is a water borne fecal contaminant, the MPE requires that potable water be used at all times and that microbiological filters be installed in water sources utilized in fumigation and general hygiene applications, that high levels of hygiene be maintained at farms and processing plants, and that employees' health be monitored for the eradication of potential risk factors.

Current Status of the MPE

With the technical aspects of the MPE fully defined and FDA's revision, PIPAA is in the process of strengthening its overall operative capacity. It is doing so by continuing to work closely with FDA and it has programmed a visit for FDA officials for November of this year.

The purpose of this visit will be to initiate PIPAA's farm and plant certification process, and to develop training courses for PIPAA's inspectors in all certification procedures in accordance to FDA's standards. Also, this visit coincides with the peak of the fall harvesting season and it will give PIPAA and FDA officials an opportunity to observe all phases of the MPE's implementation. It is noteworthy to mention that earlier this year, three farms had been singled out as already complying with all aspects of the MPE.

In addition, all raspberry producers pledged written support to the GBC in their commitment to fully implement the MPE. This effectively established the MPE as the *sole* mechanism by which exporters may export. Furthermore, the GBC organized the first field training program in one of the MPE-compliant farms. During this visit, the growers participated in the whole process of raspberry production and experienced firsthand the standards that they have to implement in order to export after March 15, 1999.

In the research area, the government of Guatemala has actively participated and has sought additional support from multilateral institutions and interested parties. For example, at the end of August, Guatemalan Ministry of Health officials participated in a week's training program at FDA's facilities in Atlanta to learn about innovative techniques for detection of cyclospora cayetanensis.

Also, PIPAA recently hosted a delegation of the Florida Department of Agriculture that had showed interest in the MPE program. As a result, they expressed their satisfaction at the program and offered their laboratory facilities to further conduct research activities in the field.

At the multilateral level, a Food and Agricultural Organization (FAO) delegation is visiting Guatemala to strengthen the quality and inocuity control systems for food commodities in the Central American and the Caribbean region. Through the University of Arkansas Food Science Institute, FAO is promoting a support network to provide training and improve research methodologies in the food safety area.

As a closing remark, the Guatemalan High Level Commission for Food Safety would like to state that it is not only determined to fully implement and observe the MPE's compliance, but to sustain the effort and perfect the program accordingly to respond to new challenges. Also, it feels that this unique kind of inter-governmental cooperation already serves as a cornerstone for programs worldwide, and that only through this kind of true cooperation will the governments be able to ensure the wellbeing of the consumers in this age of global trade.

Senate Permanent Subcommittee on Investigations
EXHIBIT # 7

List of Industry and Consumer Organizations Invited To Provide Written Statements for the Record

Industry

Mr. Steven C. Anderson
President and C.E.O.
American Frozen Food Institute
2000 Corporate Ridge, Suite 1000
McLean, Virginia 22101

Ms. Sara J. Lilygren
Senior Vice President
Legislative and Public Affairs
American Meat Institute
1700 North Moore Street, Suite 1600
Arlington, Virginia 22209

Ms. Edith Garrett
President
International Fresh-cut Produce Association
1600 Duke Street, Suite 440
Alexandria, Virginia 22314

Mr. William P. Roenigk
Senior Vice President
National Broiler Council
1015 15th Street, N.W., Suite 930
Washington, D.C. 20005

Mr. Richard Gutting
Executive Vice President
National Fisheries Institute
1901 North Fort Myer Drive, Suite 700
Arlington, Virginia 22209

Mr. Tom Zaucha
President and C.E.O.
National Grocers Association
1825 Samuel Morse Drive
Reston, Virginia 22090

Ms. Gay A. Westbrook
Manager, Legislative Affairs
National Restaurant Association
1200 17th Street, N.W.
Washington, D.C. 20036

Mr. Michael J. Stuart
President
Florida Fruit and Vegetable Association
P.O. Box 140155
Orlando, Florida 32814-0155

Mr. David Bell
Executive Director
Wild Blueberry Commission of Maine
5715 Coburn Hall
Orono, Maine 04469-5715

Mr. Matt McInerney
Senior Vice President
Western Growers Association
17620 Fitch Street
Irvine, California 92714

Consumer

Ms. Nancy Donley
President
Safe Tables-Our Priority
3110 N. Sheffield
Chicago, Illinois 60657

Ms. Mary Rouleau
Legislative Director
Consumer Federation of America
1424 16th Street, N.W., Suite 604
Washington, D.C. 20036

Mr. Brett Kay
Program Associate, Health Policy
National Consumers League
1701 K Street, N.W., Suite 1200
Washington, D.C. 20006

FRED THOMPSON, TENNESSEE, CHAIRMAN

WILLIAM V. ROTH, Jr., DELAWARE
TED STEVENS, ALASKA
SUSAN M. COLLINS, MAINE
SAM BROWNBACK, KANSAS
PETE V. DOMENICI, NEW MEXICO
THAD COCHRAN, MISSISSIPPI
DON NICKLES, OKLAHOMA
ARLEN SPECTER, PENNSYLVANIA

JOHN GLENN, OHIO
CARL LEVIN, MICHIGAN
JOSEPH I. LIEBERMAN, CONNECTICUT
DANIEL K. AKAKA, HAWAII
RICHARD J. DURBIN, ILLINOIS
ROBERT G. TORRICELLI, NEW JERSEY
MAX CLELAND, GEORGIA

HANNAH S. SISTARE, STAFF DIRECTOR AND COUNSEL
LEONARD WEISS, MINORITY STAFF DIRECTOR

United States Senate
COMMITTEE ON
GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510–6250

August 13, 1998

Mr. Steven C. Anderson
President and C.E.O.
American Frozen Food Institute
2000 Corporate Ridge, Suite 1000
McLean, Virginia 22101

Dear Mr. Anderson:

On September 25, 1998, at 9:30 a.m. in Room 342 of the Dirksen Senate Office Building, the Senate Permanent Subcommittee on Investigations will conduct a fourth hearing as part of its comprehensive investigation of the safety of foods imported into the United States. Due to time constraints, we are unable to invite all of the parties affected by this issue to testify at the upcoming hearing. On behalf of the Subcommittee, however, I am inviting you to provide a written statement for the record.

On May 14,1998, the Subcommittee held an overview hearing which focused on a General Accounting Office report entitled *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*. A second hearing was held on July 9, 1998 focusing on a case study of tainted imported fresh fruit from Central America. The Subcommittee's third hearing is scheduled for September 10th and will examine fraudulent and deceptive practices in the food import process.

The purpose of the September 25th hearing is to receive recommendations that address the inadequacies of the systems and procedures used by Federal agencies to ensure the safety of foods imported into the United States.

I understand that this is a complex issue with no easy solutions. Therefore, I am soliciting testimony from all interested parties, including Members of Congress, Executive Branch officials, and organizations representing the food industry and consumers. The Subcommittee would be interested in your assessment of the following issues, among others, that affect the safety of imported food:

1. What are the deficiencies in the current food import process and what can be done to address those problems?

2. Can the regulatory agencies better use their existing regulatory authority to improve the safety of imported food?

3. What other recommendations should be considered to improve the food import process?

To permit Subcommittee members adequate time to review the written statement prior to the hearing, please have three copies of the written statement delivered to the Subcommittee in Room 100 of the Russell Senate Office Building, Washington D.C. 20510, no later than September 11, 1998.

If you have any questions, please contact Subcommittee Chief Investigator Don Mullinax at (202)224-3721. Your cooperation is greatly appreciated in this matter.

Sincerely,

Susan Collins

Susan M. Collins
Chairman
Permanent Subcommittee
on Investigations

Senate Permanent Subcommittee on Investigations
EXHIBIT #8

National Fisheries Institute

1901 North Fort Myer Drive, Suite 700
Arlington, VA 22209
(703) 524-8880 • Fax: (703) 524-4619
E-Mail: office@nfi.org

September 15, 1998

The Honorable Susan Collins
Chairwoman, Permanent Subcommittee on Investigations
U.S. Senate Committee on Government Affairs
Washington, DC 20510-6250

Re: September 25, 1998 hearing on the Safety of Imported Food

Dear Senator Collins:

Because the safety of imported fish and seafood is of great significance to our industry, the National Fisheries Institute (NFI) greatly appreciates your invitation to provide a statement for the hearing record on food safety. The NFI represents approximately 1,000 firms that harvest, process, distribute, export and import fish and seafood products.

NFI's views on the recent report of the General Accounting Office entitled Food Safety: Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable are discussed in the memorandum to Dennis Richards of the GAO (copy enclosed). The NFI agrees with the GAO that FDA's import inspection program needs improvement, but it disagrees with the GAO assessment in so far as it relates to imported fish and seafood.

The NFI is disappointed that the GAO report fails to evaluate FDA's new mandatory fish and seafood HACCP inspection program. This new inspection system has been in force less than nine months, so it is understandable that GAO's discussion of it is cursory. The GAO, however, should not have ignored this system as a strategy to prevent violative foods from entering the U.S. marketplace. HACCP, as the National Academy of Sciences has concluded on numerous occasions, is the most effective preventative food safety system, and it is one which can work for both domestic and imported products.

Traditional FDA regulation of food imports governs shipments and not importers. FDA's new HACCP seafood inspection system, on the other hand, regulates importers as well as import shipments. In this respect, the new HACCP system is a radical departure from the general food import program described at length in the GAO report. The FAO investigation, however, failed to grasp the fundamental shift in inspection philosophy inherent in HACCP as it applies to seafood.

Under FDA's new system for seafood, for example, U.S. importers must now adhere to food safety specifications for the product(s) they import. Importers also must document that the seafood products they import were produced consistent with both the FDA's

Good Manufacturing Practices and its new HACCP regulations. Failure to comply with these new requirements places the importer and, possibly the exporter/processor on Detention Without Physical Examination status (DWPE). In this case, the product will be rejected upon entry unless there is sufficient evidence that the exporter is following FDA's packing and handling regulations. This is a very powerful way to prevent potentially unsafe product from entering the U.S.

FDA's new seafood program would be strengthened significantly if FDA to would negotiate HACCP inspection equivalency agreements. These agreements would put foreign food inspection authorities to work for the U.S. consumer, since these officials would have to demonstrate equivalent standards, enforcement authorities and compliance programs. To date FDA has received more than twenty requests to negotiate agreements and more than ten nations have submitted documents for FDA's review. Not a single agreement, however, has been signed. The NFI, therefore, urges your Committee to consider measures to facilitate FDA negotiation and implementation of HACCP equivalency agreements for fish and seafood inspection.

The NFI also disagrees with GAO's conclusion that all imported foods should be subjected to direct FDA certification. The FDA has not been able to negotiate any seafood HACCP inspection equivalency agreements to date. Negotiating similar agreements for all foods would be a much more challenging task. Nor does the FDA have the trained personnel needed to oversee inspection activities in more than one hundred countries supplying food to the U.S.

Preventing imports from countries which have not been approved as having equivalent systems, therefore, would have a devisting impact on consumers. The resulting losses would be especially painful for seafood consumers. Because domestic fisheries cannot produce the amounts needed, more than half the seafood consumed in the United States is imported. Under GAO's suggested new requirement, seafood prices would soar and consumption would fall.

The NFI also disagrees with GAO's conclusion that Customs penalties for failure to redeliver rejected merchandise are an inadequate deterrent to prevent problem importers from circumventing import controls. This is not correct for fish and seafood products. Most seafood importers sell to distributors rather than direct to retail or foodservice customs. The prices they receive for their product are far less than three times its declared value at entry, making penalties much higher than profits received from the shipment. NFI agrees that problem importers (i.e. those known to have previously circumvented the inspection system) might be required to post single entry bonds to assure penalties are adequate to deter illegal distribution of goods.

In our letter to GAO we told investigators that illegal movement of imported goods occurs in a minority of entries and, in some cases, has nothing to do with attempts to enter violative goods. The example we provided was with highly perishable fresh food. Imported fresh food sometimes has a marketable shelf life of as little as 7 days. Unfortunately, FDA often can not collect and analyze samples of fresh food entries

without substantially effecting marketability of the product. NFI can cite examples of FDA taking as much as 7 days to complete the inspection process. We have heard from member firms whose shipments were cleared after testing but could no longer market the goods because customers did not want product with little or no remaining shelf life. Freezing product is not a solution either since this reduces the value by up to 75%.

FDA sampling of frozen shipments also has been problematic. FDA reviews in some ports commonly last up to two months before an entry is released. Importers can lose all profit on such entries due to added interest and cold storage fees, especially in downward markets. The answer is more efficient inspection from FDA. FDA should have a perishable food policy mandating immediate decisions regarding sampling and specific deadlines to sample and test the products. Similarly, deadlines should be mandated for inspection of frozen entries. If the inspection process could be made more efficient fewer importers would have incentive to circumvent the system.

The following are responses to your specific questions:

1. **What are the deficiencies in the current food import process and what can be done to address those problems?**

Deficiencies were noted earlier. FDA should complete seafood HACCP equivalency agreements with the nations supplying seafood to the U.S. consumers. More FDA personnel are needed to allow FDA to carry out inspection in an efficient manner. The electronic system used for processing seafood import entries needs upgrading.

2. **Can the regulatory agencies better use their existing regulatory authority to improve the safety of imported food?**

Yes. Fully implement FDA's new seafood HACCP inspection system.

3. **What other recommendations should be considered to improve the food import system?**

FDA's inspection system for imported seafood is unique. It is based upon HACCP and should be assessed separately.

Sincerely yours,

Richard E. Gutting, Jr.
Executive Vice President

National Fisheries Institute

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TO: DENNIS RICHARDS
FROM: DICK GUTTING
RE: YOUR QUESTIONS
DATE: AUGUST 31, 1998

Enclosed are our answers to your questions. As you will see, the NFI believes that the FDA import clearance program needs substantial reform. Specifically, FDA officials must fully implement its new HACCP-based inspection program for seafood and better target its port sampling as a HACCP verification activity.

On December 18, 1997, FDA implemented with support from the fish and seafood industry, a mandatory inspection program based on the Hazard Analysis and Critical Control Point (HACCP) concept. HACCP requires seafood processors, whether domestic or foreign, to identify significant food safety hazards and control measures to prevent, eliminate or minimize them. Processors must also conduct, monitor and record specific sanitation procedures. U.S. importers must have written (documented) procedures to verify fish and seafood they introduce into U.S. commerce are produced in accordance with the HACCP regulation.

HACCP is a proactive measure taken to assure food is safe. It reduces the need for reactive measures such as port-of-entry sampling. Food safety experts from the National Academy of Science and National Advisory Committee for Microbiology of Foods recognize that end product testing cannot be conducted frequently enough to ensure food safety, given existing personnel and funding limitations.

Furthermore, end product testing is destructive and expensive, and, is best used as a verification procedure rather than a method of control.

HACCP import verification procedures strengthen FDA's import inspection system. The system would be strengthened further by the negotiation and implementation of HACCP inspection equivalency agreements between FDA and its counterparts in other countries. These agreements would provide government to government assurance that fish and seafood was produced under equivalent control systems.

Many countries have petitioned FDA to sign equivalency agreements and some negotiations have begun. However, FDA lacks the personnel resources to act expeditiously on these petitions. Nine months into the mandatory HACCP program, FDA has failed to complete a single agreement.

NFI believes international agreements would strengthen the HACCP import inspection program but has confidence the verification procedures conducted by U.S. importers augmented by periodic FDA sampling and testing provide good food safety protection.

In addition to signing HACCP equivalency agreements for fish and seafood, FDA must improve the efficiency of its traditional import inspection program. Expeditious sampling and testing of entries will minimize economic damage, therefore, reduce the temptation and need to circumvent the import inspection system. Mandatory time frames for FDA sampling, testing and review of entries must be established and met.

Aggressive efforts must be undertaken to upgrade the OASIS computer system. Upgrades should be implemented to reduce operator data input at the compliance step and allow electronic retrieval and analysis of importer, shipper and product inspection history.

Appropriation of funds must be adequate to ensure FDA personnel resources are commensurate with the inspection workload and OASIS upgrades are implemented quickly.

Thank you for giving us an opportunity to participate in GAO's study. Please call if you have questions or require further information.

Sincerely yours,

Richard E. Gutting, Jr.
Executive Vice President

NATIONAL FISHERIES INSTITUTE
RESPONSE TO GAO QUESTIONS

Question 1: To what extent are importers bypassing inspection controls?

Seafood importers know that their import shipments must comply with FDA food safety requirements and that their shipments are subject for FDA inspections. They also know that they are subject to FDA's new mandatory HACCP-based inspection system and that under this new system they must maintain written records which are subject to FDA inspection.

Based upon our communications with seafood importers the NFI believes that very few, if any, importers intend to bypass FDA inspection of shipments. Some importers, however, have on occasion introduced imported products into U.S. commerce prematurely without final clearance from the FDA. NFI does not condone this illegal activity. These events occur because of inspection delays caused by limited FDA personnel, insufficient laboratory capability and/or capacity, and a FDA electronic communication system which is not fully developed.

Many seafood entries sampled by FDA are held for an inordinate period of time. NFI receives calls on regular basis from importers experiencing port-of-entry inspection delays and other inspection related problems. Importers have reported delays of up to and exceeding six weeks on shipments of frozen product sampled by FDA. Delays of this magnitude result in significant added costs to importers and ultimately American consumers. Direct costs such as added interest payments and cold storage fees along with less obvious costs such as lost sales/customers, market devaluation and inability to secure additional credit can add up to significant amounts.

An NFI member provided the following example, pertaining to a recent entry: A shipment of 30,000 lbs. of Thailand tiger shrimp, valued at $197,160.00 was entered on June 1, 1998 and sampled on June 4, 1998. FDA did not release it until August 4, 1998 (two months later). Importer costs associated with the inspection delay were estimated as follows: market loss (the result of a falling market) over the inspection period was $18,000.00 to $20,000.00; interest cost equaled $1,500.00 to $2,000.00; and freezer storage costs were $600.00. Total costs were from $20,100.00 to $22,600.00 (10%-11.5%) of the declared value.

Financial losses resulting from FDA inspection-related delays are magnified when the seafood is fresh. Fresh seafood is typically sampled and analyzed by FDA for decomposition, or a variety of chemical analyses. While this analysis can theoretically be completed in one day, FDA sampling and analysis takes typically 2-5 days before results

are communicated to importers. The longer delays are associated with fresh shipments arriving on Saturdays for Monday morning markets. FDA does not sample or test on weekends, so when entries arrive on weekends 2 additional days of shelf life are lost.

The impact of delays up to 5 days for fresh product is very serious. For example it is not uncommon for imported fresh fish to have a shelf life of 8 days. Retailers, however, insist upon product with a 6 day sell-by date. If 5 days are lost because of FDA delays, fresh fish inspected by FDA often cannot be sold after it is officially released.

If FDA delays exceed a few days or initial shelf life is shorter, there is little or no time remaining to sell the fish after FDA completes its inspection. Fresh fish with only a few days of marketable shelf life remaining lose much of their original value. In some cases, the fish must be frozen because buyers can not be immediately found. Freezing fish under these circumstances further reduces its value. Indeed, in these circumstances we estimate that from 50 to more than 75% of the original market value of the fish can be lost as a result of FDA inspection delays. In the past, NFI has received reports from importers that entire entries of fresh fish had to be destroyed as a result of FDA inspection. Ironically, FDA test results often showed the entries were compliant.

Viewed in the context described above it is not too surprising that a small fraction of importers, particularly of perishable foods, may resort to moving entries prematurely out of the fear of serious losses from the import inspection system. While the distribution of sampled goods before official release is not acceptable, this practice is likely borne out of desperation.

Question 2: Are there specific import points in the import process that are more vulnerable to circumvention?

As previously noted, the FDA import inspection process is slow and inefficient. The resulting losses may prompt a few importer to circumvent inspection controls. FDA has improved its timeliness with fresh perishable food inspection as a result of industry pressure but continues to be erratic in meeting inspection deadlines.

The FDA should establish and be held accountable to performance standards for its import inspection program. These standards should specify criteria for sampling decisions and establish specific time frames for sending action notices for sampling, collecting and testing samples and communicating final compliance decisions. Time frames must ensure that the inspection process does not cause undue economic harm to importers or impede commerce.

The NFI has for many years petitioned the Food and Drug Administration to voluntarily abide by a strict set of procedures and inspection timeframes. For the most part, it has not adhered to timeframes and is under no statutory obligation to meet such standards. Fewer importers would circumvent the system, if FDA can be held to reasonable time frame obligations.

Importers must be allowed to take custody of their import entries by posting Customs' bonds. This is essential to transport shipments from the immediate dockside area to appropriate cold storage, designate lot codes and sample and test the entries for government and company standards when applicable. Moreover, dockside and airport storage facilities are inadequate to hold the volume of food currently offered for importation.

The FDA also should be given the necessary personnel to verify destruction and/or re-exportation of violative goods.

However, the NFI does not agree with the GAO's preliminary finding that liquidation of bonds is an inadequate deterrent to and/or penalty for moving import entries before official release. GAO's contention is that bond penalties are outweighed by the market value of the shipment. The current bond penalty rate of three times the declared value of entry is sufficient to deter fish and seafood importers. Importers rarely sell direct to end users, hence, receive wholesale prices for their entries. For fish and seafood importers profits approximate five percent of the declared value--far less than the amount of triple bond damages.

The NFI also disagrees with GAO's finding that FDA does not implement effective deterrents to repeat offenders. Serious and/or repeat violations of the FD&C Act result in "detention without physical examination" (DWPE) of the product. This procedure prevents the immediate release of goods with a history of violations. Products on DWPE are presumed to violate federal standards and can not be released until importers present analytical data to FDA showing the entry is not violative.

The GAO has suggested that test results from private laboratories examining DWPE entries are not fully reliable. However, information from two recent seafood pilot projects in New York and Los Angeles suggest otherwise. In these pilots importers were allowed to have private labs sample and test entries in lieu of FDA. When the private lab results were compared with those from FDA labs (i.e. for similar products and analysis) it was shown that private labs found violations in about the same percentage of entries.

The FDA can and does audit the results of private lab analysis on a random basis and augments these audits with periodic, on-site visits to the labs to assure that good laboratory practices are adhered to and credible testing procedures are used. The GAO noted in its report that FDA has at times found different test results than private labs. This can be explained in some cases by the limitations of analytical procedures which do not always detect microbiological contamination when it is present at low levels and not homogeneously spread throughout the product. In light of this it is possible that private labs may sometimes find violations FDA would not find.

Question 3: What can Customs and FDA do to target enforcement efforts to those importers who purposefully circumvent controls (via false invoicing or substituting) without having an adverse impact on the rest of the trade?

False invoicing is a practice that is likely designed to circumvent inspection and can not be tolerated. In response, FDA investigators should be provided electronic data systems capable of easily and effectively evaluating the inspection history of the importers, shippers and product. The OASIS system is supposed to provide this capability but currently does not. Congress should appropriate funding and direct FDA to upgrade the OASIS system.

In addition, FDA investigators should receive specialized training on how to recognize potentially fraudulent entry records. With proper training and easy, on-demand access to the inspection data, FDA inspectors will be more effective at catching offenders. Lastly, every entry offered into U.S. commerce by problem importers should be placed on DWPE status.

As previously stated, substitution can be minimized by mandating time frames for rapid efficient import inspection.

Question 4: What are our impressions of eight import controls recommended by the FD and Customs?

1) The first suggestion is unclear because we do not know what is meant by the phrase "importers with a history of violations". The NFI does not support delivery to examination stations for importers that have sometime offered goods found violative but who have not purposefully circumvented inspection. Some types of contaminants, such as mercury in some species of fish, occur naturally and vary in occurrence and concentration making periodic violations difficult to avoid.

This proposal could be useful if it targeted importers who have clearly and repeatedly circumvented the inspection program. Nevertheless, while this control might prove effective, there is the danger that insufficient CES capacity, particularly in handling refrigerated/frozen goods, will be a serious costs with little public health benefits. A less problematic approach is to place problem imports on DWPE status.

2) Requiring unique markings is impractical and will not deter firms who purposefully circumvent inspection. Violators can diminish the usefulness of marking controls by repackaging the violative product.

3) The FDA already has a policy of requiring special markings on refused products when necessary. Unless this requirement is used judiciously it unfairly penalizes honest importers who have a violative entry.

4) Judicious use of this control for importers who have repeatedly attempted to circumvent the inspection system may be a useful deterrent.

5) This proposal is unnecessary for fish and seafood, since bond penalties set at the current rate of triple the declared value are more than enough of a deterrent.

6) This proposed measure is unfair and should be rejected. For example, violations of this sort include salmonella in raw seafood. Adequate cooking of the product can eliminate salmonella in raw products. Since cooking eliminates the problem, seizure and destruction of raw products violative for salmonella would be an unjustifiable waste of valuable food.

Importers should not be penalized by destruction of their entries for violations they did not cause. It is fair to allow importers to re-export these goods, since salmonella in raw fish and seafood may not be a violation in some export countries. Alternately, product can be reconditioned.

7) No comment at this time.

8) There is no need for FDA civil penalty authority. As previously indicated, bond penalties are of adequate size to be a deterrent to seafood importers.

Representing, Educating and Promoting the Restaurant/Hospitality Industry

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NATIONAL RESTAURANT ASSOCIATION.

Senate Permanent Subcommittee on Investigations

EXHIBIT #9

STATEMENT
of the
NATIONAL RESTAURANT ASSOCIATION
on the
SAFETY OF FOODS IMPORTED INTO THE UNITED STATES
for the
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE
September 25, 1998

The National Restaurant Association appreciates the opportunity to submit this written statement for the record regarding the systems and procedures used by federal agencies to ensure the safety of foods imported into the United States. The restaurant industry has a long-standing commitment to serving safe food and training its professionals and is vitally interested in ensuring that a safe supply of imported food continues to be available for preparation and consumption.

Founded in 1919, the National Restaurant Association is the leading authority for the nation's $336 billion restaurant industry comprised of over 799,000 restaurant locations. Our members operate full-service restaurants, quick-service units and cafeterias, and provide food service for such institutions as hospitals, universities and military clubs. The Association's membership also extends to businesses that provide products and services to the restaurant industry.

The restaurant industry continues to strengthen its 25-year-old commitment and multi-million dollar investment in developing and improving food safety and has certified over one million managers in our ServSafe® training program. Today's hearing is particularly timely because September is National Food Safety Education Month (NFSEM). NFSEM was launched in 1995 by the International Food Safety Council, an industry coalition formed by the Association's Educational Foundation, to focus attention on the importance of safe food preparation in professional kitchens and at home. Because imported foods have become such a large segment of the foods Americans buy, safe food preparation and handling is dependent upon access in the marketplace to safe imported foods.

What are the deficiencies in the current food import process and what can be done to address those problems? The current federal system of imported food inspection needs to be justified, verified and focused. Adequate funding is needed to identify the extent of the problem and to subsequently conduct the number of science-based inspections and microbiological samples necessary to reliably assure international food safety. There are good and bad operators in all

countries, and Americans should be able to rely on the federal government's inspection programs at FDA to identify the bad operators and remove unsafe products from the system. This level of assurance will require a clear identification of the problem areas, along with the application of science-based concepts and increased funding over the current levels. We are not convinced, however, that these improvements warrant creation of a single food safety agency or that a single agency would be more effective than proactive coordination and harmonization of the existing regulatory agencies' food safety standards.

Can the regulatory agencies better use their existing regulatory authority to improve the safety of imported food? We strongly encourage the development of reliable foodborne illness data and a science- and risk-based import inspection system for imported foods. We should not continue to waste valuable resources on unverifiable illnesses or visual, often inadequate inspections. The greatest assurance of safety and maximum benefit will be gained by focusing efforts on identifiable illnesses and on those individual products and countries that have historically posed the greatest illness risk. Increased federal microbiological sampling must also be conducted using scientific statistical assurance techniques and not the currently used minimum or "shotgun" approaches.

What other recommendations should be considered to improve the food import process? Foodborne illness has become a major public policy issue, but not all of the public perceptions or proposed solutions are science-based or sound. Recently released data indicates that the foodborne illness estimates used by many groups to justify proposed legislation and increased governmental oversight are severely flawed and unreliable. The Centers for Disease Control (CDC), the federal agency charged with development of national foodborne illness data, states that the current published data "*should not be the basis of conclusions concerning the absolute incidence of foodborne disease.*" It is becoming quite clear that the U.S. has no reliable data to evaluate the effectiveness of current or future proposed federal controls. We strongly believe that the first step to solving any perceived problem should be the verification of the problem, and reliable illness data must be developed to do so. CDC must be directed and funded to develop reliable estimates of foodborne illness and their causes.

Assuming a problem is identified, any long-term improvement in food safety must be science- and risk-based. The best way to currently incorporate this approach into food safety systems is through the industry-developed Hazard Analysis and Critical Control Point (HACCP). HACCP is not a one-size-fits-all measure and will require industry cooperation and participation to work effectively. Voluntary HACCP with government assistance and incentives has proven to be the most effective way to incorporate HACCP and improve food safety. In cooperation with federal and state health officials, the National Restaurant Association has developed state-of-the-art model regulations and educational and informational materials based upon current science, risk and HACCP. We've actively disseminated information to our industry and customers and have worked with industry, state and local officials to adopt and incorporate new food safety regulations like the FDA Food Code.

No single comment can accurately describe the sanitary conditions found in all international food-producing countries. The conditions in individual countries will vary greatly as will the conditions on individual farms within countries. Many of the major restaurant chains and suppliers to the restaurant industry today have developed complex supplier audit systems where they inspect, set specifications and take microbiological samples of imported products. These systems are based upon HACCP and are implemented to improve safety and quality. The audits include international farm, processor and transportation inspections; microbiological sampling; and strict quality control from farm to restaurant.

Current initiatives such as trace-back to the farm of origin and country-of-origin labeling have not demonstrated that the economic impact will justify the minimal gain in food safety. These proposals concentrate efforts on identifying imported products and assessing responsibility after an illness occurs. Trace-back is clearly a system to assess blame after an outbreak. We strongly recommend that the subcommittee take a more proactive view, as discussed previously, and explore more innovative science-based solutions to prevent contaminated food from reaching the U.S. market. Country-of-origin identification may inadvertently sensationalize unfounded fears of the unknown with regard to a foreign country's sanitary conditions and may produce trade implications. From a practical standpoint in our industry, country-of-origin labeling in restaurants would be unworkable and cost-prohibitive because of the changing daily supply of menu items.

The National Restaurant Association takes a great interest in the systems and procedures used by federal agencies to ensure the safety of imported foods because, like consumers, restaurateurs rely on what is available in the marketplace. We believe that it is in our best interest to work with government, suppliers and others in the food industry to fully and honestly address this issue and assure food safety. We thank you for the opportunity to comment on these issues and would be happy to provide any additional information regarding these remarks or specific concerns of the committee.

Association of Food and Drug Officials

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Senate Permanent Subcommittee on Investigations

EXHIBIT # 10

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September 3, 1998

Mr. Timothy Shea, Chief Counsel
U.S. Senate Permanent Subcommittee
on Investigations
100 Russell Senate Office Bldg.
Washington, DC 20510

Mr. Shea:

It is indeed a pleasure to submit comments to the U.S. Senate Permanent Subcommittee on Investigations on behalf of the Association of Food and Drug Officials (AFDO) and offer our recommendation for improving the food safety system in this country.

AFDO is a one hundred and two year old organization that represents federal, state, and local government regulatory officials, many of whom are food safety and inspection program directors actively involved in efforts to implement and improve the safeguards for our nation's food supply. It is clear to AFDO that these officials believe that government at all levels must mobilize in a coordinated fashion to address the current challenges food safety presents.

AFDO does not feel there is anything more frustrating to government food safety regulators than our exclusion from the national food safety debate. Furthermore, it is very disappointing to us when we hear individuals belittle and degrade government efforts in food safety at all levels. Unfortunately, their unchallenged statements and reckless attitude cause unnecessary apprehension with the consuming public.

AFDO is also somewhat perplexed by efforts to mandate state uniformity through preemption measures which, in our view, could jeopardize a state's right to protect its citizenry and invite legal challenges to their authority. This is another matter AFDO has followed very closely in recent years.

The food safety efforts of state and local governments are clear. More than eighty percent of all food safety inspections are currently conducted by state and local governments. Foodborne illness investigations, food samples for bacteriological and chemical defects, investigations of consumer complaints, and industry compliance or enforcement efforts are primarily performed at the state and local levels.

A national food safety system cannot be run by the federal government alone and it must include the approximately seventy state food safety agencies and three thousand local jurisdictions. State and local government inspectors, investigators, epidemiologists, lab technicians, veterinarians, and others involved in public health need to be deputized to work as part of a national integrated food safety system.

The enclosed document entitled "Food Safety VINE (Vertically Integrated National Enterprise) An AFDO Vision" is presented to the Permanent Subcommittee on Investigations as AFDO's recommendation for what we believe the future national food safety system should resemble.

AFDO will continue its pursuit of this plan through our dialogue with federal counterparts, industry, and consumers. We hope that the Subcommittee and other government policy makers will consider this plan and recognize the value of unifying the current available food safety resources into an "army" for fighting foodborne illness and advancing food safety.

Please feel free to direct any questions on this proposal to my attention.

Sincerely,

Joseph Corby, President
Association of Food and Drugs Officials

JC:aa

Enclosure

FOOD SAFETY VINE (VERTICALLY INTEGRATED NATIONAL ENTERPRISE)

AN AFDO VISION

Today's food safety regulatory structure is a system that consists of multiple government oversight of the food industry and the foods they produce, distribute, and sell. This system, with an infrastructure that includes federal, state, and local government as participants, has served the public extremely well and we proudly boast to have the safest food supply in the world. While the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are viewed as the major food safety regulatory agencies in the United States, it is state and local government programs that conduct more than 80% of the food establishment inspections, investigate the majority of foodborne illnesses, and sample the majority of food products for bacteriological or chemical defects. This is an enormous task and responsibility.

To ensure the public of a safe, wholesome, and properly represented food supply, an effective food safety system must be a combined effort of the food industry, the government (at all levels) and the consumer. Surveillance, research, risk assessment, effective regulations with science-based regulatory standards, appropriate inspection, enforcement and compliance activities, training and education must be the cornerstones of any future food safety system. If there is a system breakdown resulting in foodborne illness, the industry must have the willingness and government must have the flexibility and the capacity to move swiftly to determine the cause of the illness, remove the implicated product from the marketplace, and build in strategies to prevent future recurrences.

Does such a system need to be invented? No, this system is already in place today. *Is the system perfect?* No, but over the years it has continually improved and it has allowed the development of one of, if not, the safest, most abundant, most diverse, and most convenient food supply.

Can our current food safety system be improved? Absolutely, but the Association of Food and Drug Officials (AFDO) believes that we do not need to start over from ground zero -- we need to determine more effective ways to enhance the synergism of and to strengthen the effectiveness of the federal, state, and local infrastructure currently in place.

When President Clinton announced the Food Safety Initiative to this country much was said about the role of the federal government to assure the consuming public safe and wholesome food. Originally there was little said about state and local food safety efforts despite the mammoth amount of work that has been done there, and the availability of abundant resources. As a result, AFDO decided to mobilize with their affiliates and state partners and proclaim that no real debate about a national food safety system could exist without including state and local jurisdictions. AFDO has spoken at conferences, seminars, and training workshops where they remind everyone about the enormous resources available in state and local programs. Recently a vision by AFDO was developed detailing their views as to what a national food safety system could and should be. We call the system Food Safety VINE (Vertically Integrated National Enterprise). We use the acronym VINE as a handy way of describing a joint effort of federal, state, and local food safety organizations. AFDO is aggressively promoting and articulating Food Safety VINE and the impact we believe it can have on improvement to and resource maximization for food safety in this country.

There are two key words within the acronym VINE - **vertically** and **integrated**. A **vertical** system is one, which functions from the top to the bottom. At the top of the system we envision the federal government providing leadership through surveillance, technical support, setting of standards, risk assessment, evaluation of programs, certification of field personnel, training, and additional funding where needed. We believe the role of the states and local governments would be to perform domestic inspections, investigations, and collections of samples. Furthermore, we believe it is the responsibility of the federal government to provide the proper regulatory oversight of imported foods at entry point levels. By allowing states and local government agencies to handle domestic food safety affairs the federal government can increase its oversight of imported food, which, in our view, is desperately needed. State and local governments should also continue their licensing programs and strong enforcement activities as they see fit. The vision of a vertical system is really a vision of coordination and uniformity resulting in the elimination of duplicative efforts and better utilization of all current dedicated food safety resources.

An **integrated** system is a vision of joining these resources into a unified organization. It would include centralizing current and available knowledge relative to food safety such as specific information on animal health, foodborne illness, food establishment inspections, and sample analysis. AFDO also believes an integrated system would include tracking mechanisms for foodborne illness and food defects, which can be monitored by all states and local jurisdictions electronically.

To AFDO, whether the food safety system is implemented by an independent single agency or by multiple agencies is not the key to improving our overall system. What is vitally important, however, is the need to take a new look at our food safety system and to fundamentally change from our current concept of a "federal system" and a "state/local system" to a fully integrated "national system." As a prerequisite to accomplishing this task, the roles and responsibilities of each federal agency involved with various aspects of food safety, as well as the roles and responsibilities at the state and local levels must be explicitly defined. Once these roles are clear at the federal level, the roles of the counterparts at the state and local levels will fall into place over time.

AFDO has chosen to use the word Enterprise in its acronym for we believe this is a daring and comprehensive plan. We shall solicit input from all potential players in this strategy, including government, industry, and academia. We are currently working very closely with FDA to better develop and clarify the concept of this plan.

AFDO concurs with the National Academy of Sciences' "Committee to Ensure Safe Food from Production to Consumption" where they recommend in their 1998 report that:

"The National Food Safety Plan should:

- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for research and surveillance to:
    - monitor changes in risk or potential hazards brought on by changes in the food supply or consumption patterns; and
    - improve the capability to predict and avoid new hazards;

- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne disease and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize and provide support for the burdens imposed on state and local authorities that have primary front-line responsibility for the regulation of food service establishments; and
- address consumers' behavior related to safe food handling practices."

The dwindling resources available for government services mandate that government at all levels develop effective ways to work smarter and more cooperatively in the regulation of food. The states and federal agencies have a long history of working together through various cooperative agreements, contracts, grants, memoranda of understanding and, most recently, partnerships. AFDO believes the time is right to get beyond partnerships and for all major stakeholders at the federal, state, industry, and consumer level to work to develop a "blueprint" for the establishment of a truly vertically integrated national food regulatory system.

ACIL

Senate Permanent Subcommittee on Investigations

EXHIBIT #____11____

September 22, 1998

The Honorable Susan M. Collins
Chairwoman
Permanent Subcommittee on Investigations
United States Senate
Washington, DC 20510

Dear Senator Collins:

ACIL, the American Council of Independent Laboratories, is the trade association representing private testing firms including laboratories that perform FDA-mandated import testing. ACIL shares your concerns regarding certain aspects of the American food import system and commends you for your in-depth examination of the issue.

The role of private laboratories has been touched on, but not fully discussed during the hearings you have led on this issue. I believe that an explanation of the role of private laboratories in the import process might be useful in the subcommittees deliberations.

FDA has several classifications for food imports depending on their risk to consumers. Some foods are categorized as needing sampling without physical examination. For these foods, importers must submit laboratory results to FDA proving that the product is safe for consumers. The private laboratory is selected by the importer as is the sample to be tested. The private - laboratory conducts the appropriate analysis and submits the results for review to FDA. FDA then reviews the package sent by the private laboratory and makes a decision on whether to release the shipment into commerce.

Concerns surrounding the propriety of allowing importers to provide the samples to be tested and the opportunity for fraud during sampling have also been raised during hearings. Currently, FDA does not mandate third-party testing. Clearly, this is a major flaw in the current import regulations. ACIL recommends that the laboratory that will perform the testing also be responsible for sampling of imported products. Private laboratories are well-versed in the nuances associated with sampling and would provide further assurance of an unbroken chain of custody.

At times some at FDA have questioned whether private laboratories are really impartial. ACIL's member laboratories are pledged to uphold the highest ethical standards. However, ACIL also recognizes the possible appearance of conflict of interest and has long supported an accreditation scheme for import testing laboratories.

-More-

1629 K STREET, NW, SUITE 400, WASHINGTON, DC 20006 202/887-5872 FAX 202/887-0021

In fact, ACIL and a coalition of industry groups and federal government observers, including FDA officials, have developed an accreditation standard for food testing laboratories which would provide FDA with assurance that import testing laboratories are capable of generating accurate data with which the agency could make compliance decisions with.

The accreditation criteria, developed by the Food Laboratory Accreditation Working Group (FLAWG), will serve as the basis for accrediting food laboratories in the United States. The criteria follow International Standards Organization (ISO) Guide 25, which lays out generic standards for any kind of laboratory. ISO is widely recognized as the premier standard setting organization in the world and many companies tout their ISO certification in their marketing literature. The FLAWG standard is now managed by AOAC, International, a highly respected association in the food-testing field. I have enclosed copies of the criteria for your review.

The FLAWG standards are already being used as the basis for food laboratory accreditation by the American Association for Laboratory Accreditation (A2LA). A2LA has numerous international mutual recognition agreements and laboratories in the United States receiving A2LA accreditation are recognized internationally, meaning that data from tests performed by A2LA-accredited laboratories are recognized by regulatory authorities around the world.

In order to receive accreditation, officials from A2LA conduct a comprehensive audit of the facility wishing to receive accreditation. After correcting deficiencies and implementing quality systems acceptable to A2LA, a laboratory can market itself as being accredited.

The FLAWG criteria are by no means minimum standards. They are extremely stringent and many laboratories will choose not to become accredited or will be incapable of doing so. USDA's Food Safety and Inspection Service has already indicated that its laboratories will pursue accreditation. FDA has said it is considering accreditation for its laboratories.

Accreditation would allow FDA to increase the volume of imports it tests through the utilization of private laboratories to do more tests and to be more confident in the data private laboratories provide. While FDA would continue to handle its current volume of tests, private laboratories could be used, at the importers cost, to perform testing on a greater number of products.

Implementing an accreditation program for private laboratories would be simple and would cost the American taxpayer very little. FDA could rely on private-sector accrediting bodies like A2LA to assess the competence of testing laboratories. Those laboratories that pass muster could be placed on an FDA list from which importers could choose. Importers would continue to pay for the costs of testing.

ACIL believes that this one improvement could greatly enhance the safety of the imported food supply for the American consumer at little cost. I would be happy to discuss this matter with your staff at greater length. I can be reached at 202/887-5872.

Sincerely,

Joseph O'Neil
Executive Director

encls.

Senate Permanent Subcommittee
on Investigations

EXHIBIT #_____12_____

U.S. Customs Service
Responses to Supplemental Questions for the Record
Hearing Before the
U.S. Senate Permanent Subcommittee on Investigations
September 24, 1998
Improving the Safety of Food Imports

Question 1, part 1. When an FDA-regulated shipment has been refused entry, the importer has the option of destroying it instead of exporting it. You testified that at some ports, the destruction occurs at some location other than the port of entry, and that Customs does not have the resources to confirm the destruction. Does this mean that an unscrupulous importer at those ports could sell his rejected food shipment in the U.S. without any possibility of being caught?

Answer: The fact that Customs cannot witness all destructions does not mean that an unscrupulous importer can sell rejected food without any possibility of being caught. In fact, Customs does require documentation confirming that destructions have occurred for all shipments required to be destroyed. Additionally, while all ports may not witness all destructions, some destructions are witnessed thus increasing the risk to the importer of getting caught. Customs may also receive information from other sources regarding an importer's practices which could prompt an investigation. Finally, if an importer were to submit a false statement regarding the destruction of a refused shipment he or she would be liable for criminal and civil sanctions in addition to an assessment of liquidated damages.

Question 1, part 2. Can you estimate the scope of this problem?

Answer: We cannot precisely estimate the scope of the problem. Our experience has been that the number of importers who repeatedly violate food safety regulations is small in comparison to all importers and that the number of shipments refused entry for health and safety reasons is very small in comparison to all food shipments.

Question 1, part 3. At how many ports does the destruction occur at some locations other than the port of entry?

Answer: Destruction of food shipments does not occur at any of the ports of entry. Destructions typically occur at a local landfill or an incineration plant. Therefore, an inspector must travel to the destruction site in order to witness the destruction and then return to the port. As I indicated in my testimony, this is a resource intensive requirement that all ports are not capable of meeting.

Question 2. You referred to "enhanced technology" that will allow Customs to track shipping containers from the port of entry. Could you describe that technology being developed?

Answer: In my testimony, I discussed the use of markings which are visible under ultraviolet light. Customs is also beginning to use transponders attached to containers that provide a way to track the container from the port of entry to the importer's premises or the centralized examination station.

Additional information regarding the use of bonded warehouses.

As I stated in my testimony, Customs does not have the legal authority to require an importer to use a bonded warehouse. We are currently looking at the use of centralized examination stations, in cooperation with the Food and Drug Administration, to determine whether sampling can occur at these locations and the resource implications for both agencies in doing so.

Senate Permanent Subcommittee on Investigations
EXHIBIT # 13

RESPONSES BY THE FOOD AND DRUG ADMINISTRATION (FDA OR THE AGENCY) TO SUPPLEMENTAL QUESTIONS SUBMITTED FOR THE RECORD FROM SENATOR JOSEPH LIEBERMAN

SEPTEMBER 24, 1998 HEARING ON IMPROVING THE SAFETY OF IMPORTED FOODS BEFORE THE SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

Question 1. We've learned that one of the reasons it has been so easy for food importers to trick FDA inspectors is because there are no identification marks that associate FDA-regulated shipments with the import entry documents filed with Customs. Why is that?

Currently, there is no explicit statutory authority to require such "identification marks" on incoming shipments of food. As we stated in our testimony at the September 24th hearing, FDA is considering a regulation to require refused food to be marked when the food is exported, rather than destroyed, as an added control to prevent the attempted re-importation of violative food. We believe that the most effective mechanism to prevent importers from avoiding FDA review and/or examination, e.g., by substitution, however, is through improving cargo control and coordination with the U.S. Customs Service (Customs). FDA and Customs, in response to the General Accounting Office (GAO) findings, already have begun to plan operations to allow the agencies to better coordinate activities in this area. Plans to better assure the redelivery or destruction of refused food also are being developed.

Question 2. Can you explain why, according to the GAO, the Customs Department was so often unaware of FDA's refusal notices? For example, the GAO reported that at the Los Angeles and New York ports, Customs was unaware of the refusal notices more than 60% of the time. According to a Customs employee, these shipments would not be properly disposed of, leading to the entry of rejected foods into U.S. commerce.

We have followed up on this finding, which concerned us as well. Our New York District Office confirmed the GAO finding of a communication problem between FDA and Customs. In that District, FDA was not properly forwarding the refusal notices to Customs. This problem has been corrected. Based on information from our Los Angeles District Office, however, all refusal notices were sent to, and received by, the appropriate Customs office. Our contacts with other FDA Districts did not find any similar problems.

Question 3. Whether you call it equivalency authority or something else, how would it work in practice for the FDA to monitor the food safety systems in other countries? Comparing your mandate to that of FSIS, for example, is it realistic that you engage in similarly intrusive inspections or comprehensive document analyses when you are responsible for a much greater variety of foods in a much larger number of countries?

As you know, the authority proposed in S. 1707, "The Safety of Imported Food Act," would provide FDA with the authority to deem food adulterated, and thus, to deny importation, based on a finding that food prepared under a foreign food safety system does not meet U.S. food safety requirements or the system does not otherwise achieve the level of protection required. With this authority, FDA would, as part of its normal planned surveillance of imported foods, perform evaluations of systems, conditions, and measures applied by foreign governments and industries to assure that food offered for import into the U.S. meets the requirements of the Act and achieves the level of protection required for such food prepared, packed, and held in the United States. These evaluations would be done on a systematic basis as follows:

- The evaluations would be done for a given country by focusing either on a specific producer or industry, or on the country's food safety system as a whole. This approach recognizes that:

  a. the requirements for the safe production of different foods are different and must be evaluated on an individual basis. For example, the requirements for the production of safe fresh or frozen seafood differ significantly from such requirements for fresh produce, and both of these will differ from the requirements to produce safe processed foods;

  b. different food industries are likely to be regulated by different authorities in foreign countries. For example, fresh produce may be regulated by the Ministry of Agriculture while seafood may be regulated by the Ministry of Fisheries. In each instance, the regulatory authority and infrastructure of the responsible authority may be significantly different and thus require independent evaluation; and

  c. the depth, level, and frequency of such evaluation will vary based on the facts stated in a and b, as well as criteria such as described below.

- The systematic evaluation would include the following actions:

  a. identify and classify food groups by public health risk presented;

  b. establish priorities by country, industry, or food (or a combination of such factors) judged to present a high health and safety risk, based on criteria including:

-potential health risk associated with a particular food or method of processing,
-volume of particular food exported to the U.S. by each country, and
-existence of U.S. health and safety standards applicable to the commodity; and

c. Assign foods that are classified as a low health and safety risk a low priority for in-country evaluation or determine that no evaluation is needed.

- The timeframe for completing these evaluations would be dependent on resources available.

FDA recognizes that a restructuring of the Agency's traditional, end-product inspection-based approach to imported food safety toward a system based on preventing food safety problems before they occur will not be straightforward or simple. FDA also recognizes that such efforts will require resources beyond those presently available to the Agency. The 1999 budget increase for food safety will help. Fundamental changes are necessary, nevertheless, to ensure in an efficient and sound manner that foods available in the U.S., whether they originate domestically or abroad, are safe.

In response to your question regarding whether it is realistic for FDA to have an inspection system similar to that of the Food Safety and Inspection Service (FSIS) for monitoring food safety systems in other countries, the answer is no. As you correctly noted, our regulatory responsibilities include a greater variety of foods in a larger number of countries. FSIS is able to inspect the foreign plants that export FSIS-regulated commodities to the U.S., and approve only those that meet FSIS criteria, prior to exportation. Due to the breadth of commodities FDA regulates, together with the limitations on our resources, FDA intends to focus on products that pose the greatest risk to public health. This risk-based strategy is described above.

Question 4: Along the same lines, how would you monitor various nations' agriculture practices? If the FDA had the authority to require that imported produce be grown under the same safety standards as in the US, what specifically would growers have to do?

FDA has been working with the U.S. Department of Agriculture (USDA) to develop a survey of domestic farm production based on the FDA/USDA Good Agricultural Practices voluntary guidelines. The Good Agricultural Practices describe basic sanitation practices used in the United States. The survey's goal is to develop data that describes these general practices for the most common fruits and vegetables in the United States. Our timetable is to conduct a pilot study in 1999 in two states, New York and California, of approximately 30 commodities. Based on this data, the survey would be refined, and in 2000, we would conduct a national survey of approximately 14 states.

Our plans for technical assistance and initial assessments are that FDA, in partnership with other agencies, will provide selected countries with outreach, education, training, and technical

assistance to help assure that imported products meet U.S. standards. The Good Agricultural Practices and surveys could be used by farmers to learn how U.S. farmers interpret U.S. standards. In Fiscal Year 1999, emphasis will be placed on produce to promote the implementation of the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." These activities will be coordinated with USDA's Foreign Agricultural Service. FDA intends to address the needs of domestic growers through outreach and education working in conjunction with USDA's Cooperative State Research, Education, and Extension Service.

On the international level, FDA is working through the Codex Alimentarius (Codex) Commission's Food Hygiene Committee to establish international sanitation standards that are consistent with U.S. standards, including voluntary guidelines such as the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." Furthermore, FDA and USDA have conducted numerous international workshops and public meetings to inform and educate our foreign government and industry counterparts about this food safety strategy. Given the voluntary nature of these guidelines, our strategy is to educate and provide technical assistance both to domestic and foreign producers and to work through Codex to establish international standards consistent with reducing foodborne illness linked to microbial contamination of fresh fruits and vegetables. Lastly, as we better understand the means and mechanisms of microbial contamination from the Food Safety Initiative's scientific research and risk assessment investigations, we in turn will provide additional and substantive guidance, regulation, or standards, as appropriate.

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Senate Permanent Subcommittee on Investigations
EXHIBIT # 14

RESPONSE OF THOMAS J. BILLY, ADMINISTRATOR of FSIS, TO SUPPLEMENTAL QUESTIONS FOR THE RECORD SUBMITTED BY SENATOR JOSEPH LIEBERMAN (D-CT)

Hearing Before The
U.S. Senate Permanent Subcommittee on Investigations
September 24, 1998
IMPROVING THE SAFETY OF FOOD IMPORTS

1. **Compared to the FDA, the FSIS is clearly doing a thorough job regulating the imported foods for which it is responsible. Could that be partly because the FSIS has a more limited variety of foods within its jurisdiction, as well as far fewer shipments to inspect? Does the FSIS receive a disproportionately large amount of resources, compared with the FDA, to carry out its food import inspections?**

FSIS enforces the Federal Meat Inspection Act, Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry, and egg products prepared for distribution in commerce for use as human food. Because FSIS has a legal responsibility to continuously inspect meat, poultry and egg products in domestic plants processing these products, the Agency must assure the American public that it has equivalent oversight of any meat, poultry, or egg product that enters the United States as an import.

Compared to domestic production, the amount of meat, poultry, and egg products imported into the United States is very small. Imported meat accounts for only about 7 percent of domestic consumption; imported poultry totals less than 1 percent; and imported egg products also totals less than 1 percent. However, every one of these shipments of imported products are subject to reinspection upon entry to the U.S. and must have undergone inspection in the exporting country under a system certified by FSIS as equivalent to the FSIS inspection system. At this time, only 36 countries are certified as meeting our standards.

Being that foreign countries are required to have systems of inspection equivalent to the United States inspection system, the bulk of inspection costs are placed on the foreign country. FSIS import reinspection resources are used to 1) determine the equivalence of a foreign country's inspection system, and 2) to reinspect foreign product before it may enter the United States.

For FY98, FSIS spent an estimated $10.6 million on import reinspection. This amounts to about 2 percent of FSIS' total appropriation for FY98. I am unaware of the amount of FDA's budget allocated for import inspection and would defer that question to FDA.

2. **Given the greater variety of non-poultry and non-beef products for which the FDA is responsible, do you believe that FSIS' equivalency system could be adapted by the FDA?**

FSIS' equivalency system is mandated by the Agency's responsibility to assure that U.S. consumers only receive meat, poultry and egg products that are safe, wholesome, and accurately labeled. Therefore, at FSIS, we use a two-part process to determine that eligible foreign countries maintain inspection systems that are equivalent to the U.S. system.

The first part of the process, *document analysis*, is an evaluation of the country's laws, regulations, and other information pertaining to its inspection system. The second part of the process, *on-site reviews*, involves actual on-site audits of foreign countries, including randomly picked plants within the country, to ensure the country's inspection system is equivalent to the U.S. system.

If FSIS determines that a foreign country's inspection system is equivalent to the U.S. system, the country is eligible to export meat or poultry to the United States. If FSIS determines that a foreign country is not meeting standards equivalent to those of the United States, we take appropriate action. This can include delisting a country from the list of those eligible to export to the U.S. Or, if the issue is determined to be less serious, we immediately initiate communication with the country's inspection officials to discuss the problems found.

We are aware that FDA forwarded legislation to Congress representing the approach they would like to take in regard to the safety of food imports other than meat, poultry, and egg products. The legislation was introduced in the Senate by Senator Barbara Mikulski (S. 1707) and in the House by Congresswoman Anna Eshoo (H.R. 3052).

3. **The National Academy of Sciences report issued last month recommends the creation of a single food safety framework, headed by a single person with control of resources for all food safety activities. What is your response to that idea? Does it make sense that the U.S. Department of Agriculture is responsible for imported meats while the Food and Drug Administration is responsible for imported produce?**

As you may know, the President created a Council on Food Safety to develop a comprehensive strategic plan for Federal food safety activities and to ensure that Federal agencies annually develop coordinated food safety budgets. One of the Council's first orders of business will be to review the National Academy of Sciences (NAS) report, "Ensuring Safe Food from Production to Consumption." After providing the opportunity for public comments, including public meetings, the Council will report back to the President within 180 days with its response to the NAS report. We are analyzing the study and will carefully consider any suggestions for improving our food safety efforts, in conjunction with the public comments received.

Senate Permanent Subcommittee on Investigations
EXHIBIT # 15

Response to Supplemental Questions for the Record

Questions Submitted by Senator Joseph Lieberman (D-CT)
Following Hearings Before The
U.S. Senate Permanent Subcommittee on Investigations
September 24, 1998

Response Submitted by Sanford A. Miller, Ph.D.
Representing
Committee to Ensure Safe Food from Production to Consumption
National Academy of Sciences
October 21, 1998

Thank you for providing the opportunity for me to respond to supplemental questions regarding the testimony I provided on behalf of the National Academy of Sciences Committee to Ensure Safe Food from Production to Consumption during the hearings before the U.S. Permanent Subcommittee on Investigations on September 24, 1998. I am pleased to respond to questions posed by Senator Lieberman.

1. Your prepared testimony states, "It is by no means clear that imported food, as a class, poses greater risks than does domestically produced food." Could you elaborate on that? Are you aware of any data comparing the safety of domestic and imported foods?

While the committee did not find specific data for a direct comparison of the safety of domestic versus imported food, it is clear that Americans are consuming more imported foods today than 25 years ago. On a per capita basis, Americans are consuming more fruits and vegetables today (31 lbs more commercially grown vegetables and 24 lbs more fresh fruit) than in 1970. As the consumption of and demand for fresh fruits and vegetables have increased, so has the importation of these items. The GAO (1998) reports that in 1995, one-third of all fresh fruit consumed in the United States was imported. Paralleling the increase in imported fresh food items, fresh produce was identified as the leading vehicle associated with foodborne disease outbreaks in Minnesota from 1990 to 1996, accounting for almost one-third of all outbreaks. Similarly, over 50 percent of the fish and shellfish consumed in the United States is imported and a personal communication to the committee from the Centers for Disease Control and Prevention in June 1998 elucidated that shellfish alone caused 21 percent of all reported foodborne illnesses from 1978 to 1992.

When attempting to make comparisons between domestic and imported food safety, it is important to consider the fact that the production, processing, and shipment of food produced in the United States can, in theory, be subject to government monitoring from field to consumer, but imported food is not subject to the same oversight. In addition,

federal officials cannot use the same methods to regulate imported food that they use—or that would make sense—to regulate domestically produced food.

In addition to these factors, there are other issues that the committee did not explicitly discuss. Among these is the great variation in safety and quality control in different countries and regions. For example, one could compare Western Europe and Southeast Asia in terms of the application of quality control and safety technology.

2. You correctly point out that sample analysis techniques used by the FDA do not provide a means for detecting many of the most serious risks to consumer health using as an example the outbreak caused by the undetectable cyclosporiasis parasite that contaminated Guatemalan raspberries. How effective would an equivalency requirement be in preventing outbreaks of this type?

The application of an equivalency requirement would assure than an exporting country was applying controls that would assure the same degree of safety as in the United States. The laws that FSIS and FDA administer require that imported food meet the same standards as domestic food. But the enforcement approaches of the two agencies to meet this common requirement are quite different. The different systems of scrutiny of imports used by FDA and USDA largely mirror their different approaches to domestically produced food as is required since they must document domestic equivalence. USDA statutory authority requires meat and poultry food safety systems of exporting countries to be equivalent to the U.S. system. FDA currently lacks the authority to require that imported foods be produced under a system equivalent to the one that it administers domestically. Federal efforts controlling imported foods are currently targeted to meet the problems of past violations, in which contamination, processing defects, labeling, and quality are at issue. Current domestic U.S. practice is directed towards a prevention model (HACCP) rather than reaction. In my personal opinion, satisfaction of the requirement for an acceptable HACCP plan would provide appropriate assurance for meeting equivalency standards. Without firm knowledge of most significant risks, for development of a HACCP plan, it is impossible to know whether an equivalency requirement would be effective. Therefore, in my opinion, the first step in this process must be research to identify hazards, and estimate risks for foods produced by our trading partners. This is not necessarily the view of the committee, which did not try to outline specific methods for equivalency determinations.

Not all agencies responsible for monitoring the safety of imported food are authorized to enter into agreements with the governments of exporting countries in order to reciprocally recognize food safety standards or inspection results. Uniform or harmonized food safety standards and practices should be established, and officials allowed to undertake research, monitoring, surveillance, and inspection activities within other countries. This should permit inspection and monitoring efforts to be allocated in accordance with science-based assessments of risk and benefit.

3. Why did your committee recommend the elimination of our continuous inspection system for meat and poultry?

The underpinning for this recommendation stems from the committee's primary recommendation:

Base the food safety system on science.

The committee recognizes that this philosophy must be integrated into all aspects of the food safety system, from federal to state and local. The committee also recognizes that to effectively base the food safety system on science, there are statutory changes needed. Thus, the committee recommends that:

Congress should change federal statutes so that inspection, enforcement, and research efforts can be based on scientifically supportable assessments of risks to public health.

Accordingly, changes in the federal statutes that would foster and enhance a science-based system recommended by the committee include:

• *Eliminate continuous inspection system for meat and poultry* ***and replace*** *with a science-based approach which is capable of detecting hazards of concern.*

Continuous carcass-by-carcass inspection may have been appropriate for the food hazards that were present 70 years ago. However, threats to food safety have changed dramatically and the current regulatory effort that is embedded in statute, to physically examine each meat and poultry carcass, is not a science-based approach that is responsive to the food safety hazards of today. This statutory requirement does not allow allocation of regulatory efforts in ways that correspond to the health risks presented by contemporary sources of food or modern means of food production and processing. In short, the hazards of greatest concern today are microbiological and chemical contamination and these hazards are not detectable with the traditional continuous inspection system. In addition, the committee provided another of a needed statutory change: mandate a single set of science-based inspection regulations for all foods. Nevertheless, in my opinion, carcass inspection should not be entirely deleted, rather it should be done on a selective basis using appropriate sampling techniques. The report emphasizes that the statutory requirement that mandates continuous inspection precludes a science-based determination of when continuous inspection is appropriate and when it is not useful.

Further, changes in statutes or organization should be based on a rational, well-developed national food safety plan formulated by current federal agencies charged with food safety efforts and with representation from the many stakeholders involved in ensuring safe food. Such a plan, as shown below, should serve as the blueprint for strategies designed to determine priorities for funding, to determine what the needs are, and to ensure that they are incorporated into activities and outcome evaluation.

The National Food Safety Plan should:
- include a unified, science-based food safety mission;
- integrate federal, state, and local food safety activities;
- allocate funding for food safety in accordance with science-based assessments of risk and potential benefit;
- provide adequate and identifiable support for the research and surveillance needed to:
  - — monitor changes in risk or potential hazards created by changes in food supply or consumption patterns, and
  - — improve the capability to predict and avoid new hazards;
- increase monitoring and surveillance efforts to improve knowledge of the incidence, seriousness, and cause-effect relationships of foodborne diseases and related hazards;
- address the additional and distinctive efforts required to ensure the safety of imported foods;
- recognize the burdens imposed on state and local authorities that have primary front-line responsibility for regulation of food service establishments; and
- include a plan to address consumers' behaviors related to safe food-handling practices.

4. Your committee recommended the creation of a single food safety agency. Can you explain how it reached this determination?

The National Academy of Sciences' Committee to Ensure Safe Food from Production to Consumption evaluated the current system and found that the fragmented regulatory structure is not well equipped to meet the current challenges. The varying mandates and missions of the different agencies responsible for food safety make it difficult for a single set of science-based regulations to be developed and implemented (see page 9 of the committee's report). Thus the committee recommended a statutory-based, unified, central framework for managing the federal food safety program, which is headed by a single official and which has the responsibility and control of resources for all federal food safety activities (see Recommendation IIIa below); however, the committee did not explicitly recommend the creation of a single food safety agency.

Recommendation IIIa: To implement a science-based system, Congress should establish, by statute, a unified and central framework for managing federal food safety programs, one that is headed by a single official and which has the responsibility and control of resources for all federal food safety activities, including outbreak management, standard-setting, inspection, monitoring, surveillance, risk assessment, enforcement, research, and education.

This recommendation envisions an identifiable, high-ranking, presidentially-appointed head, who would direct and coordinate federal activities and speak to the nation, giving federal food safety efforts a single voice. The structure created, and the person heading it, should have control over the resources Congress allocates to the food

safety effort; the structure should also have a firm foundation in statute and thus not be temporary and easily changed by political agendas or executive directives. It is also important that the person heading the structure should be accountable to an official no lower than a cabinet secretary and, ultimately, to the President.

Many members of the committee were of the view that the most viable means of achieving these goals would be to create a single, unified agency headed by a single administrator—an agency that would incorporate the several relevant functions now dispersed, and in many instances separately organized, among three departments and a department-level agency. The committee did not determine categorically that a single agency was the only structure that would provide a unified, central framework, with the characteristics described in Recommendation IIIa. Designing the precise structure and assessing the associated costs involved with creating a single agency or other structures was not possible in the time frame given the committee, nor were they included in its charge. The committee did discuss other possible structures and while it ruled out some, it certainly did not and could not examine all possible configurations within the time frame desired. It was for this reason that the committee strongly endorsed the statutory recommendation for a follow-up study directed towards the issue of structure.

The committee did not believe that the type of centralized focus envisioned can be achieved through appointment of an individual with formal coordinating responsibility but without legal authority or budgetary control for food safety, a model similar to a White House-based "czar". Nor, in the committee's view, can this goal be achieved through a coordinating committee similar to that currently provided via the National Food Safety Initiative. In evaluating possible structures, the committee realized that past experience with other structures or reorganizations, including the creation of new agencies, such as the Environmental Protection Agency, should inform any final judgment. Further, it is quite possible that other models may now exist in government that can serve as templates for structural reform. Whether or not a single agency emerges, the ultimate structure must provide for not just delegated responsibility, but also for control of resources and authority over food safety activities in the federal government.

Senate Permanent Subcommittee
on Investigations
EXHIBIT #_____16_____

SUPPLEMENTAL QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR DANIEL AKAKA (D-HI)
Hearings Before The
U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
September 24, 1998
IMPROVING THE SAFETY OF FOOD IMPORTS

DR. RICHARD LEVINSON
American Public Health Association

★★★

Our previous hearings have explored the problems associated with foodborne illnesses. We heard from expert witnesses testifying on inadequate entry-control systems for imported food. We have seen that federal efforts to ensure the safe importation of foods are unreliable and inconsistent according to a study by the General Accounting Office, and we learned that fraud and deceit were commonplace problems.

One problem area that has yet to be explored fully are pesticides banned in the United States that are still being used overseas. As we develop a comprehensive approach to the importation of food, we cannot forget about unsafe levels of pesticides and/or chemical residues found in imported foods. Nor can we forget that America's consumers are not the only ones at risk. America's farmers suffer as well. Every time a pesticide is banned in the United States because of health reasons, our farmers must turn to alternative farming practices, which are often more expensive. Yet the farmers overseas do not operate under the same restrictions and the FDA, which is responsible for the safety of most imported foods, can only provide visual inspection of these items.

I would like to ask you whether you believe there is a risk to American consumers from imported food sources because of pesticides determined to be unsafe in the United States?

If so, what should be done about the problem?

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American Public Health Association

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October 21, 1998

Response to question for the record.

Timothy J. Shea
Chief Counsel and Staff Director
Permanent Subcommittee on Investigations
Committee on Governmental Affairs
United States Senate
Washington, DC 20510-6250

Dear Mr. Shea:

This letter is to respond to your question of me in your letter of October 8, 1998 regarding a potential risk to American consumers from imported food sources produced with pesticides determined to be unsafe in the United States.

Pesticides and chemical residues represent important public health issues. From the testimony delivered during the series of hearings held by Senator Collins, the American Public Health Association believes it is likely that food produced abroad using U.S.-banned pesticides is entering our markets. This possibility exists, we believe, because of existing inadequacies in our imported food safety system.

The extent of the risk that such imports might pose is difficult to determine because of the wide number of pesticides and combinations of pesticides that are used and the varying levels that might be found on imported foods. However, it is hard to imagine that any food product containing pesticide residues banned in the U.S. could be said to offer an "equivalent" level of safety to food that does contain them.

As a matter of prevention, our imported food safety inspection system should require foreign governments and producers to affirmatively demonstrate that adequate safeguards exist in their production systems to ensure that foods are not produced using substances banned for safety reasons in the U.S. Additionally, the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) need to have a testing and inspection program in place that can ensure that foreign producers are meeting their food safety obligations. While USDA apparently does a good job of ensuring this, FDA would clearly need additional resources and an expansion of its exiting statutory authority to allow it to adequately evaluate and monitor foreign production systems to ensure they provide equivalent safety to the United States'.

Sincerely,

Richard A. Levinson

Richard A. Levinson, MD, DPA
Associate Executive Director for Programs and Policy

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125 Years of Leadership in Public Health

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